

Molecular hydrogen: phase III and long-term clinical evidence

Evidence audit dated September 19, 2026. Scope: molecular hydrogen (H₂), including hydrogen-rich water, hydrogen-generating tablets, inhaled gas, hydrogen-containing intravenous solutions, dialysate, and organ-preservation solutions.

Evidence overview

Phase III-labelled hydrogen studies exist, but the label should not be mistaken for confirmatory evidence. The identified [ClinicalTrials.gov](https://clinicaltrials.gov) records include four phase III studies and two combined phase II/III studies; their actual or intended enrollment ranges from 2 to 60 participants, and one is an uncontrolled pilot. A seventh study, Hydro-COVID, is called phase III in its peer-reviewed publication although its registry phase field is “Not applicable.” ([Obesity registry](#), [elderly cognition registry](#), [Parkinson’s registry](#), [stroke registry](#), [rectal-cancer registry](#), [transplantation registry](#), [Hydro-COVID publication](#), [Hydro-COVID registry](#))

No replicated, adequately powered positive phase III or completed multi-year placebo-controlled evidence was identified that establishes the broad marketed metabolic, cardiovascular, or neurological benefits of consumer hydrogen products. This is an assessment of the retrieved evidence, not proof that every possible formulation is ineffective: small studies report selected positive outcomes, but the larger Parkinson’s trial was negative, the strongest multi-year cardiovascular signal was observational, and the largest phase III-labelled placebo-controlled trial was negative for its primary endpoint. ([Parkinson’s evidence](#), [multi-year dialysis study](#), [Hydro-COVID](#), [metabolic pilot](#))

The most defensible positive interpretation is preliminary, indication- and formulation-specific clinical signals, not established treatment or prevention of disease. FDA has explicitly challenged hydrogen-water disease claims, and FTC requires health advertising to reflect the quality, relevance, and totality of the human evidence rather than selected favorable studies. ([FDA warning letter](#), [FTC Health Products Compliance Guidance](#))

Scope and search methods

Eligibility and interpretation

- **Phase criterion:** Include records explicitly labelled phase III or phase II/III, plus publications explicitly describing themselves as phase III. Record disagreements between registry and publication rather than silently choosing one.
- **Multi-year criterion:** At least 24 months of intended participant follow-up or reported long-term outcome assessment, not merely recruitment across several calendar years. Planned but uncompleted follow-up is labelled separately.

- **Contextual evidence:** Include important 12–18-month studies and shorter placebo-controlled trials when needed to interpret metabolic, cardiovascular, and neurological claims. These do not become “multi-year” merely because they are called long-term.
- **Excluded interventions:** Hydrogen peroxide, hydrogen sulfide, hydrogen chloride salts, hydrogen breath testing, and drugs whose chemical descriptions merely contain the word hydrogen. Animal experiments and isolated case reports are not clinical trials.
- **Statistical interpretation:** A significant change from baseline is not evidence of superiority to placebo. Secondary endpoints, subgroup findings, and observational associations are kept distinct from prespecified primary randomized comparisons.
- **Missing information:** “n.a.” means not available or not verifiable in the retrieved material, not necessarily that the information never existed.

Sources and coverage

PubMed-indexed publications were sought using molecular-hydrogen, hydrogen-rich-water, hydrogen-gas, phase-III, randomized-trial, long-term, and duration-specific searches, followed by primary-paper and reference checking. [ClinicalTrials.gov](https://clinicaltrials.gov) was searched and its structured records retrieved; a broad synonym search returned 1,879 candidates before intervention-specific screening, including many irrelevant chemical, drug, and dental records. Cochrane Library was searched for relevant CENTRAL records and systematic-review material, with indexed web discovery used where its native content was restricted.

The registry search expression was "molecular hydrogen" OR "hydrogen-rich" OR "hydrogen gas" OR "hydrogen water" OR "hydrogen inhalation" OR "hydrogen enriched". Registry phase fields, outcome time frames, enrollment, status, and posted results were checked against publications where available; registry status was not assumed to be current clinical activity when the last update was old.

This is a comprehensive evidence audit of identifiable records, **not a PRISMA systematic review or a guaranteed exhaustive database export**. Native PubMed search-page retrieval failed, some Cochrane content was restricted, and the original 2018 Parkinson’s results article was not fully accessible; these limitations prevent an unqualified claim that every unpublished or poorly indexed trial has been captured. The Parkinson’s protocol, PubMed record, and later primary paper were used together, without inventing inaccessible numerical results. ([Parkinson’s protocol](#), [2018 PubMed record](#), [later primary trial discussing the result](#))

Regulatory interpretation below uses U.S. FDA/FTC standards primarily, with an EU food-additive distinction. It is not a worldwide approval inventory or product-specific legal opinion.

Phase III and phase II/III inventory

Design, sample size, duration, and endpoints

Study and condition	Phase and design	Sample size	Participant exposure/follow-up	Primary endpoint
NCT02832219: obesity/metabolic fitness	Registry phase III; randomized crossover; registry quadruple masking, publication describes double-blind pilot (registry , publication)	Registry: 12 actual; publication: 10 overweight women. These are different reported populations, not interchangeable denominators (registry , publication)	Oral hydrogen-generating minerals; 4-week comparison, not multi-year (publication)	Change in body-fat percentage from baseline to 4 weeks (registry)
NCT02830854: cognition in older women	Registry phase III; single-group, open-label, not randomized and no placebo (registry)	13 actual (registry)	4 weeks of 3% H ₂ inhalation; registry says 20 min/day, publication says 15 min/day (registry , pilot publication)	Registry: change in ADAS-Cog, including cognitive-domain scores (registry)
NCT03971617: Parkinson's disease	Phase II/III; randomized, placebo-controlled, quadruple-masked registry design (registry)	Planned 70; actual 2 , one per arm (registry and results)	Hydrogen-generating tablet water twice daily for 52 weeks; outcomes at week 56 (registry)	Treatment-emergent adverse events; motor function, quality of life, and cognition were secondary (registry)
NCT03320018: acute ischemic stroke	Phase II/III; randomized, triple-masked; hydrogen plus minocycline versus corresponding placebos (registry)	15 enrolled; 14 randomized: 6 active, 8 placebo (registry)	Hydrogen intravenously or orally for 3 days; minocycline for 5 days; follow-up 90 days (registry)	Favorable 90-day simplified modified Rankin Scale outcome, with threshold based on baseline stroke severity (registry)
NCT04713332: rectal-cancer radiotherapy adverse effects	Phase III; randomized, participant-masked; hydrogen water, vitamin E, and placebo arms (registry)	60 estimated; actual n.a. (registry)	Hydrogen water 250 mL three times/day; 8 weeks (registry)	Blood count and multiple oxidative/inflammatory biomarkers, including Nrf2, SOD, CAT, GST, MDA, TNF, MMPs (registry)

Study and condition	Phase and design	Sample size	Participant exposure/follow-up	Primary endpoint
NCT02613195: older donor liver/kidney transplantation	Phase III; randomized, triple-masked; hydrogen-rich versus conventional Celsior preservation solution (registry)	20 estimated; actual n.a. (registry)	Graft storage/exposure 2–4 hours; clinical outcomes up to 6 months (registry)	Changes in AST/ALT, bilirubin, creatinine, and GFR (registry)
Hydro-COVID, NCT04716985: outpatient COVID-19	Publication: phase III; registry: not applicable. Randomized, blinded, multicenter, placebo-controlled (publication , registry)	700 randomized; 675 in day-30 dataset; 667 in primary efficacy comparison: 334 H ₂ , 333 placebo (publication)	250 mL hydrogen water twice/day for 21 days; primary assessment day 14, main published follow-up day 30; later questionnaires planned through 12 months (publication)	Composite clinical worsening: fatigue, dyspnea, oxygen requirement, hospitalization, or death (publication)

Results versus placebo and evidentiary status

Study	Statistically significant outcomes versus placebo	Null findings, limitations, and status
Obesity/metabolic fitness	Reported body-fat reduction 3.2% versus 0.9%, p=0.05 , a borderline result; arm-fat index reduction 9.7% versus 6.0%, p=0.01; triglyceride reduction 21.3% versus 6.5%, p=0.04; fasting insulin –5.4% versus +29.3%, p=0.01 (publication)	Weight, BMI, and body circumferences did not differ significantly. Very small pilot, several outcomes, short duration; does not establish durable weight loss or diabetes prevention; registry completed, no tabular registry results (publication , registry)
Older-women cognition	Not assessable: no placebo. MMSE improved 14.2%, p<0.01; selected ADAS-Cog tasks improved, but these are uncontrolled pre/post findings (pilot publication)	Completed; small, unblinded pilot susceptible to practice effects and other bias. Phase III registration does not turn this into confirmatory efficacy evidence (registry)
U.S. Parkinson's trial	No interpretable efficacy comparison. Posted primary data show 0 treatment-emergent adverse events in each one-person arm; secondary outcome data withheld because of low-enrollment privacy concerns (posted results)	Terminated for insufficient enrollment ; last update April 12, 2023. It is incorrect to describe this as an ongoing 70-person efficacy trial or as a successful phase III study (registry)
Stroke: H₂ plus minocycline	Favorable primary outcome in 1/6 active versus 1/8 placebo ; no inferential p-value or confidence interval posted for that comparison (registry results)	Completed; last update December 19, 2023. Too small for a reliable efficacy conclusion; the combination design cannot attribute any effect specifically to H ₂ (registry)
Rectal-cancer radiotherapy	n.a.; no results posted or matched outcome publication verified (registry)	Unknown status; last known recruiting, last update February 17, 2021. Biomarker protocol is not proof of reduced clinical radiation injury (registry)

Study	Statistically significant outcomes versus placebo	Null findings, limitations, and status
Transplant preservation	n.a.; no results posted or matched human outcome publication verified (registry)	Unknown status; last known not yet recruiting, last update November 24, 2015. Listed background articles are not evidence of successful completion of this human trial (registry)
Hydro-COVID	No primary benefit: worsening in 46.1% versus 43.5%; HR 1.09, 90% CI 0.90–1.31 , p=0.479. One secondary sleep comparison had nominal p=0.047, with both medians 5; it is not evidence of prevention of clinical worsening (publication)	No demonstrated reduction in hospitalization/oxygen requirement or death. Registry status is unknown, last known active/not recruiting, despite a published completed analysis; publication is the appropriate source for outcomes (publication , registry)

The small positive metabolic pilot is therefore a genuine placebo-controlled signal, but not a robust confirmatory demonstration simply because its registry says “phase III.” Conversely, Hydro-COVID supplies a comparatively large, clinically relevant negative result, although it addresses infection rather than chronic metabolic or neurological disease. ([Metabolic publication](#), [Hydro-COVID publication](#))

Multi-year studies and planned long-term follow-up

Completed long-term outcome evidence

Study / condition	Sample and design	Exposure and observation	Primary or main endpoint	Findings and placebo interpretation
Nakayama et al., 2018: chronic hemodialysis; cardiovascular/cerebrovascular outcomes	309: H ₂ -enriched dialysis 161, conventional dialysis 148; prospective, nonrandomized, unblinded observational study, not a randomized clinical trial (full paper)	Dialysate containing 30–80 ppb H ₂ , three sessions/week; mean observation 3.28 years (full paper)	Composite all-cause mortality plus nonfatal cardiovascular/cerebrovascular events (full paper)	41 versus 50 composite events; adjusted HR 0.59, 95% CI 0.38–0.92 ; exact adjusted p n.a. in retrieved text. All-cause death alone did not differ; not superiority to placebo , and residual confounding remains (full paper)

Study / condition	Sample and design	Exposure and observation	Primary or main endpoint	Findings and placebo interpretation
NCT02918188: steroid-refractory/dependent chronic graft-versus-host disease	Published phase II, multicenter, open-label, single-arm study; 24 patients ; registry still lists 21 estimated (publication , clinical review)	Hydrogen water 4 mL/kg three times/day; 12-month response assessment and estimated 4-year survival ; this does not mean every participant completed four years (publication , clinical review)	Overall response across affected organ domains (publication)	Response 18/24, 75%, 95% CI 55.1%–88%; estimated 4-year survival 74.7%, 95% CI 54.9%–94.5%. Responders versus nonresponders: 86.6% versus 0% survival, p=0.000132, not H₂ versus placebo ; cannot demonstrate a causal survival benefit (publication)

The dialysis study is the clearest genuinely multi-year comparative signal in the cardiovascular domain, but it is observational and uses a specialized dialysis intervention. It cannot substantiate a claim that drinking hydrogen water prevents heart attacks, strokes, or death in the general population. ([Dialysis study](#))

Registered multi-year endpoints without verified definitive long-term results

Study / condition	Design and sample	Duration and endpoint hierarchy	Verified status / results
NCT07411911: neonatal hypoxic-ischemic encephalopathy	Phase I; randomized, outcome-assessor-masked; 54 estimated; 2% inhaled H ₂ plus standard care versus standard care, not sham gas (registry)	H ₂ for 72 hours; primary feasibility at 72 hours and safety at 30 days; secondary neurodevelopmental assessment at age 24–36 months using Bayley-4 (registry)	Not yet recruiting in last update February 17, 2026; no results posted. Multi-year follow-up is planned, not demonstrated benefit (registry)
NCT04175301: high-grade glioma during radiotherapy	Phase II; randomized, quadruple-masked, placebo-controlled pilot; 15 estimated (registry)	Hydrogen-generating water five times/day for 6 weeks; QoL, cognition, performance, survival/PFS through 24 months . Primary endpoint is feasibility/enrollment, listed over 3 years, not 3 years of H ₂ treatment (registry)	Active/not recruiting; last update July 29, 2025; no posted results. Supports neither tumor control nor neuroprotection claims at present (registry)

Study / condition	Design and sample	Duration and endpoint hierarchy	Verified status / results
NCT03818347: cancer rehabilitation	30 actual; registry says randomized and investigator-masked, but also “single group” despite experimental and analogue-machine arms: internally inconsistent design fields (registry)	Hydrogen/oxygen inhalation 3 hours/day, described as long-term; primary sleep/diet/exercise and immune outcomes at 3 months; secondary PFS at 1 year and overall survival at 3 years (registry)	Registry completed, last update October 19, 2020; no posted results. Registered start-to-completion dates span roughly two years, so actual 3-year follow-up cannot be assumed (registry)
Nishimaki et al.: mild cognitive impairment, originally planned for two years	Randomized, double-blind, placebo-controlled; 81 randomized, 73 analyzed: H ₂ 35, control 38 (full paper)	Originally planned 2 years , stopped after 1 year because of the 2011 tsunami; actual mean intake about 320 mL/day; ADAS-Cog primary cognitive outcome (full paper)	No overall significant ADAS-Cog benefit; small APOE4 subgroup, 7 H ₂ versus 6 control, had significant cognitive findings; exact subgroup p-values n.a. in retrieved text. Not completed multi-year efficacy evidence (full paper)

A two-year report in advanced Alzheimer’s disease describes only **one patient**, without placebo or randomization, and is therefore excluded from the clinical-trial inventory. Its duration does not overcome the inability of a case report to establish efficacy. ([Two-year case report](#))

Important longer and shorter trials that do not meet the strict multi-year criterion

Neurological and cardiovascular evidence

Study	Sample, duration, comparator	Endpoint and results	Interpretation
Yoritaka et al., 2018: Parkinson’s disease	178 participants; multicenter double-blind placebo-controlled trial; 1 L/day hydrogen water for 72 weeks , with planned observation to week 80 (protocol)	Primary: change in total UPDRS at week 72; subsequent primary publication states the trial showed no UPDRS benefit . Exact between-group estimate/p-value n.a. in accessible material (2018 record , later trial discussion)	Particularly important negative replication of earlier small positive studies; longer than one year, but less than two years (protocol , later trial)
HYBRID II: coma after out-of-hospital cardiac arrest	73 randomized: H ₂ 39, control 34; 2% H ₂ for 18 hours , outcomes 90 days ; multicenter double-blind trial (publication)	Primary good neurological outcome, CPC 1–2: 56% versus 39%, p=0.15 . Secondary 90-day survival: 33/39 versus 20/33 , 85% versus 61%, p=0.02; median mRS 1 versus 5, p=0.01 (publication)	Promising secondary signals, failed primary endpoint , prematurely stopped because of pandemic enrollment restrictions. “II” in the acronym is not proof of regulatory phase II or III; recruitment over several years is not multi-year follow-up (publication)

Study	Sample, duration, comparator	Endpoint and results	Interpretation
Ono et al., 2023: Alzheimer's disease inhalation pilot	8 treated; nonrandomized open-label, untreated database comparators: 19 for cognition, 5 for imaging; 6 months treatment plus 12 months off treatment, 18 months total (full paper)	At 6 months, ADAS-Cog change -4.1 versus +2.6 in untreated patients; imaging comparison p=0.001. Benefits were not significant at the final one-year post-treatment follow-up; no formal primary endpoint verified (full paper)	Not placebo-controlled, too small for disease-modification claims, and not a two-year trial (full paper)
Yoritaka et al., 2021: Parkinson's inhalation	20 enrolled, 15 analyzed after adherence exclusions; 16-week randomized double-blind placebo-air comparison (full paper)	Primary MDS-UPDRS total change: H ₂ +1.9 versus placebo +0.8; p>0.05 ; no demonstrated motor, QoL, or biomarker superiority (full paper)	Small and underpowered, but another negative controlled result rather than support for Parkinson's treatment (full paper)
HydrogenFAST, NCT05574296: pediatric ECPR	Phase I safety/feasibility protocol; 56 planned including 3 nonrandomized vanguard patients; 53 randomized; usual-care control (protocol)	H ₂ for 72 hours; primary safety at 30 days, functional follow-up at 6 months; registry includes hospitalization/survival assessments up to 12 months; no efficacy results (protocol , registry)	Experimental clinical research. A multiyear project and activated IND do not mean multiyear treatment, positive results, or marketing approval (protocol)

Metabolic and risk-factor evidence

Study	Design, sample, duration	Statistically significant versus placebo/control	Qualifications
LeBaron et al., 2020: metabolic syndrome	Double-blind placebo-controlled RCT, 60 , 30 per arm; 24 weeks (full paper)	Treatment×time interactions: total cholesterol p<0.001, triglycerides p<0.01, glucose p<0.01, HbA1c p<0.001, BMI p<0.001; several inflammatory markers also significant (full paper)	No clear primary/secondary hierarchy in the article; numerous outcomes, no cardiovascular-event or diabetes-complication endpoint. LDL p=0.06 , not significant; HDL fell rather than rose despite a significant interaction, p=0.01 (full paper)
Electrolyzed hydrogen water metabolic-syndrome RCT, 2024	Randomized double-blind filtered-water-controlled trial; 181 , 3 months (PubMed)	No significant overall difference reported; favorable waist-circumference result limited to high-physical-activity subgroup; exact p-value/CI n.a. in abstract (PubMed)	Counters a blanket claim of consistent metabolic benefit; subgroup and directional biomarker findings are not an overall positive efficacy result (PubMed)
Song et al., 2015: hypercholesterolemia	Double-blind placebo-controlled randomized trial, 68 , 34 per arm; 10 weeks , 0.9 L/day (PubMed)	Favorable cholesterol-response and HDL-function findings; exact between-group p-values and CIs n.a. in retrieved abstract (PubMed)	Surrogate and ex-vivo outcomes, not evidence of fewer heart attacks or strokes; plasma HDL-cholesterol did not increase (PubMed)

Study	Design, sample, duration	Statistically significant versus placebo/control	Qualifications
Hydrogen inhalation in hypertension, 2024	Retrospective propensity-matched observational analysis, 2,364, 24 weeks; routine antihypertensives with versus without H ₂ (PubMed)	Week-24 between-group SBP difference -7.81 mmHg , 95% CI -9.57 to -6.04; DBP -2.89 mmHg, 95% CI -4.24 to -1.54 (PubMed)	Large sample does not eliminate confounding; not randomized or placebo-controlled , not multi-year, and not proof that H ₂ can replace antihypertensive therapy (PubMed)

For scale, the 24-week metabolic study reported HbA1c changing from 5.8% to 5.1% with H₂ versus 6.2% to 6.1% with placebo, and triglycerides from 189.8 to 142.4 versus 184.4 to 185.6 mg/dL. These are potentially interesting findings, but multiple biomarker comparisons and a modest sample require confirmation before extrapolating to diabetes treatment, weight-loss efficacy, or prevention of vascular events. ([Full metabolic trial](#))

A 2025 hydrogen-dialysis study also had only 12 months of follow-up: 92 enrolled, 81 completed, with no randomized control group. Its fatigue and metabolomic findings do not add a new multi-year placebo-controlled cardiovascular efficacy trial. ([2025 dialysis study](#))

What Cochrane contributes

The Cochrane Library contains a **CENTRAL trial record** for the 24-week metabolic-syndrome RCT. CENTRAL inclusion means that a trial is indexed; it is not a Cochrane endorsement of its results or a high-certainty systematic-review conclusion. ([CENTRAL record](#))

The Cochrane systematic review of bladder pain syndrome includes a hydrogen-water trial with 30 **randomized** and 28 **analyzed participants**, an 8-week placebo-controlled regimen, and symptom/pain outcomes. The original trial found **no significant symptom benefit versus placebo**, despite pain improving within both groups; this is outside the requested disease domains and duration threshold but illustrates why pre/post improvement must not be called placebo superiority. ([Cochrane review trial characteristics](#), [original trial](#))

No dedicated Cochrane synthesis establishing a high-certainty metabolic, cardiovascular, or neurological benefit of molecular hydrogen was located in the accessible searches. This is a search finding, not a claim that Cochrane has formally evaluated and rejected every hydrogen indication.

Marketed health claims: evidence and regulatory assessment

How to read these flags

“Supported,” “preliminary,” and “experimental” below are **evidence-assessment categories**, not a claim that FDA has assigned each indication an official label. FDA regulates product intended use and approval; FTC regulates the substantiation and presentation of advertising claims, including how preliminary evidence is qualified. ([FDA hydrogen-water warning](#), [FTC guidance](#))

For this report, “rigorously supported clinical claim” requires more than a statistically significant biomarker: sufficiently robust controlled evidence, clinically relevant benefit, applicable formulation/dose/population, and consistency with the rest of the evidence. This framework follows the relevant principles in FTC guidance, but is not a substitute for an agency approval determination. ([FTC guidance](#))

Marketed claim	Evidence flag	Clinical assessment and regulatory implication
“Treats diabetes,” “reverses insulin resistance,” or “prevents metabolic disease”	Preliminary; disease-treatment claim not established	Small short-term randomized biomarker signals exist, but no verified positive multi-year or adequately powered confirmatory outcome trial establishes these broad claims; the larger 3-month metabolic trial was not positive overall (24-week RCT , 181-person RCT). A disease-treatment claim is not legitimized by supplement positioning or a disclaimer (FTC guidance).
“Causes substantial or lasting weight loss”	Not rigorously supported	The phase III-labelled obesity pilot did not show significant weight or BMI superiority; selected body-fat and metabolic changes are not evidence of sustained clinically important weight loss (pilot).
“Lowers cholesterol and prevents heart attacks/strokes”	Preliminary lipid effects; prevention claim unproven	Lipid and ex-vivo HDL signals do not establish reduced cardiovascular events; long-term dialysis results are observational and population-specific (lipid trial , dialysis study). FDA’s hydrogen-water warning specifically cited claims about stabilizing cholesterol and fighting inflammation as part of the products’ unlawful disease-related marketing (FDA letter).
“Treats high blood pressure”	Preliminary/experimental adjunct	Observational blood-pressure changes do not establish a causal placebo-controlled effect or support substitution for antihypertensives (hypertension study).
“Improves survival or brain recovery after cardiac arrest”	Experimental; promising secondary signal	HYBRID II’s secondary survival and disability findings warrant further trials, but its primary neurological endpoint was not significant; intensive-care inhalation results cannot be transferred to consumer water or tablets (HYBRID II).
“Treats or slows Parkinson’s disease”	Not established; larger controlled trial negative	The 72-week trial found no UPDRS benefit; the U.S. phase II/III trial enrolled only two; another inhalation RCT was negative (later primary paper reviewing the water trial , U.S. registry).
“Prevents Alzheimer’s,” “reverses dementia,” or “improves memory”	Preliminary/experimental	MCI trial overall negative, with only 13 APOE4 carriers in the favorable subgroup; other studies are very small or uncontrolled, including the phase III-labelled cognition pilot (MCI trial , cognition registry , AD pilot).
“Treats stroke”	Experimental	Posted phase II/III results show only one favorable primary outcome in each arm, and active treatment combined H ₂ with minocycline; isolated hydrogen efficacy is not established (stroke registry).
“Prevents COVID-19 worsening”	Not supported by the identified phase III trial	Hydro-COVID did not beat placebo on its primary endpoint or establish reduced hospitalization/death; the conclusion is specific to the tested oral regimen and population (Hydro-COVID).

Marketed claim	Evidence flag	Clinical assessment and regulatory implication
“Protects against radiation,” “treats cancer,” or “extends cancer survival”	Experimental/unproven	The identified phase III radiotherapy and multiyear glioma/rehabilitation registrations do not provide verified definitive efficacy results (radiotherapy registry , glioma registry , rehabilitation registry). FDA specifically challenged hydrogen-water radiation-protection claims (FDA letter).
“Powerful antioxidant/anti-inflammatory that improves overall health or slows aging”	Biomarker signals preliminary; broad clinical/longevity benefit unproven	Selected markers changed in short studies, but that does not establish fewer illnesses, slower human aging, or longer life; some significant findings were not favorable and some were null (metabolic trial , clinical review).

What is legitimately supported?

The evidence supports narrowly worded research statements such as: “Some small controlled studies found changes in selected metabolic biomarkers,” “a dialysis cohort found an adjusted association with fewer composite events,” and “a cardiac-arrest trial found encouraging secondary outcomes but did not meet its primary endpoint.” Those statements retain the limitations of the underlying studies; they are not equivalent to an established consumer health benefit or permission to market a disease treatment. ([Metabolic RCT](#), [dialysis cohort](#), [HYBRID II](#), [FTC guidance](#))

None of the broad therapeutic claims in the table reaches the report’s rigorously supported category. This judgment concerns efficacy claims; it does not deny that individual positive observations are real reported findings, and it does not assert that every tested hydrogen intervention has the same effects. ([Clinical evidence review](#), [Hydro-COVID](#), [Parkinson’s evidence](#))

Regulatory distinctions that matter

- **FDA disease claims:** In its June 14, 2022 H2 Beverages warning letter, FDA concluded that the cited claims established intended disease uses, making the products unapproved new drugs and misbranded drugs; it stated that the products were not generally recognized as safe and effective for the referenced uses. This is a product-specific enforcement example, not a ban on every hydrogen beverage. ([FDA warning letter](#))
- **FTC evidence standard:** Health claims generally require competent and reliable scientific evidence, typically randomized controlled human testing with appropriate sample, duration, outcomes, and clinically meaningful results; advertisers must consider contrary evidence rather than cherry-pick favorable findings. ([FTC guidance](#))
- **“Preliminary” is not a cure-all disclaimer:** FTC explains that words such as “promising,” “preliminary,” “may,” and “helps” may inadequately communicate substantial limitations; a disclaimer cannot contradict an otherwise unsubstantiated treatment claim. ([FTC guidance](#))
- **Food safety is not therapeutic efficacy:** EFSA’s re-evaluation concluded that hydrogen E949 as a food additive did not raise a safety concern under the evaluated uses; it did not approve hydrogen as treatment for metabolic, cardiovascular, or neurological disease. ([EFSA E948/E949 re-evaluation](#))

- **Research authorization is not marketing approval:** HydrogenFAST's protocol reports an activated investigational new drug application and phase I testing. Those are research permissions and study characteristics, not proof of clinical effectiveness or authorization for broad consumer claims. ([HydrogenFAST protocol](#))

Overall clinical interpretation

The evidence base contains legitimate randomized trials, negative results, positive exploratory signals, stale registry records, and unusually small studies labelled phase III. The central evidentiary gap is not an absolute absence of human research; it is the lack of replicated, adequately powered, clinically meaningful positive evidence supporting the breadth of common consumer claims. ([Phase III obesity pilot](#), [Parkinson's registry](#), [Hydro-COVID](#), [clinical review](#))

Across the requested domains, metabolic effects remain mainly short-term surrogate findings; cardiovascular benefit is suggested by a confounded dialysis cohort and secondary cardiac-arrest outcomes; neurological evidence includes negative larger Parkinson's results and small exploratory cognitive studies. No finding justifies treating consumer hydrogen water, tablets, and inhalation devices as interchangeable, or using them to replace established care. ([Metabolic trial](#), [dialysis study](#), [HYBRID II](#), [Parkinson's evidence](#), [MCI trial](#))

The most useful future studies would prespecify clinically meaningful primary outcomes, recruit adequate samples, measure delivered H₂ exposure, use credible masking and matched comparators, report all registered outcomes, and follow participants long enough to establish durability and safety. Until those gaps are filled, the appropriate interpretation is **experimental clinical use and preliminary consumer-benefit evidence**, not established disease treatment.