Dihexa phase 1 2 or 3 trials

Dihexa itself has not progressed through standard phase 1, 2, or 3 human trials, and there is no approved, completed clinical development program for it as of 2025.[1] [2] [3] [4]

Current trial status

- Dihexa has been studied extensively in **preclinical** models (cell and animal studies) showing cognitive and synaptic benefits, but long-term safety (including tumorigenic risk via c-Met activation) has not been established.[5] [6] [1]
- Reviews and clinical overviews in 2024–2025 state that Dihexa has **not yet entered large-scale, double-blind, placebo-controlled clinical trials**, and there is no record of completed phase 1, 2, or 3 programs in humans.[2] [3] [1]

Related compound (fosgonimeton)

- Fosgonimeton (ATH-1017), a pro-drug of Dihexa developed by Athira Pharma, has undergone phase 1 and phase 2/2-3 trials in Alzheimer's disease, but this is a distinct, patented clinical candidate rather than Dihexa itself.[7] [8] [4] [9]
- These fosgonimeton trials do not change the fact that **Dihexa, as the peptide itself, remains at the preclinical/experimental stage** and is not in an advanced regulatory development pathway.[3] [4] [7]

Practical implications

- There is no regulatory-approved indication, dosing, or safety profile for Dihexa, and its use in humans is considered off-label/experimental in some private practices rather than part of formal phase 1–3 trials.[10] [2] [3]
- Anyone considering Dihexa is relying on animal data and informal clinical use, not on completed, peer-reviewed phase 1–3 trial evidence or any FDA/Health Canada approval.[1] [2] [3]

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are there any human trials planned

There are no registered, formal human phase 1–3 trials of Dihexa currently planned or announced, and no active development program for it appears in major trial or pipeline listings as of late 2025.[21] [22] [23]

Dihexa itself

- Recent reviews and clinic overviews describe Dihexa as still limited to preclinical work and off-label use, explicitly noting that it has not yet entered formal, large double-blind human trials and that such trials remain “pending” or “expected” rather than scheduled.[22] [21]
- No ongoing or upcoming Dihexa studies are listed in major public trial registries (for example, ClinicalTrials.gov), and expert summaries emphasize the absence of any established human dosing protocol because it has “never advanced to human clinical trials.”[23] [22]

Related drug fosgonimeton (ATH-1017)

- Fosgonimeton, a Dihexa-related HGF/MET modulator from Athira Pharma, completed phase 2/2-3 Alzheimer’s trials but failed primary endpoints; by 2025 development has been **discontinued**, with the company shifting focus to other HGF-pathway compounds.[24] [25] [26]
- With fosgonimeton halted and no Dihexa entries in trial registries, there is currently no clear, publicly announced path toward new human trials of Dihexa or its direct prodrugs.[26] [21] [24]

What exists instead

- Dihexa is being used experimentally by some functional and regenerative medicine practices, which collect informal case data rather than running regulated clinical trials.[27] [21]
- Foundations have historically funded preclinical Dihexa work (for example, Parkinson’s disease models), but these efforts are described as determining “clinical potential” rather than initiating human studies, and no follow-through human trial has been posted.[28] [29]

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