

A prospective single-arm cohort study is a type of observational clinical study with the following characteristics:

□ **Definition:** A prospective single-arm cohort study follows a group of participants over time without a comparison (control) group, where all participants receive the same treatment or intervention, and outcomes are measured forward in time from the point of enrollment.

□ **Key Components:** **Prospective:** Data is collected forward from a defined starting point (e.g., initiation of treatment).

Single-arm: There is only one group in the study; no randomization or control/placebo group.

Cohort: A defined group of individuals with shared characteristics (e.g., disease, treatment) is followed over time.

Study purpose: Often used to assess feasibility, safety, or efficacy of an intervention in early-phase clinical research.

□ **Example Use Case:** Evaluating the safety and outcomes of a new surgical technique in 100 patients with Chiari I malformation, all treated the same way and followed for 12 months ¹⁾

△ **Limitations:** No control group limits ability to attribute causality.

Susceptible to bias (e.g., selection bias, confounding).

Results are hypothesis-generating, not confirmatory.

¹⁾

Henry LC, McDowell MM, Stephenson TL, Crittenden JB, Byrd AL, Fernández-de Thomas RJ, Chang YF, Nowicki KW, Mantena R, Strick PL, Friedlander RM. Predecompression and postdecompression cognitive and affective changes in Chiari malformation type I. *J Neurosurg.* 2025 Feb 21;143(1):4-12. doi: 10.3171/2024.8.JNS241363. PMID: 39983117.

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