

Clinical trials of foramen ovale closure for post stroke in all type of patients

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1 Percutaneous closure of patent foramen ovale

| Trial | Treatments | Patients | Trials design and methods |
|---|---|---|--|
| Device for PFO closure vs medical treatment | | | |
| CLOSE <i>ongoing</i> [NCT00562289] n=NA follow-up: | Devices for PFO closure versus aspirin | - | Parallel groups |
| CryptoCard <i>ongoing</i> [NCT01018355] n=NA follow-up: | Device closure of PFO followed by medical treatment versus antiplatelet therapy | elderly patients above 50 years of age with a patent foramen ovale and a history of cryptogenic stroke or TIA | open Denmark |
| GORE HELEX vs medical treatment | | | |
| REDUCE <i>ongoing</i> <i>unpublished</i> [NCT00738894] n=NA follow-up: 2 years | GORE HELEX Septal Occluder plus antiplatelet versus antiplatelet medical management alone | patients with a patent foramen ovale and history of cryptogenic stroke or imaging-confirmed TIA | Parallel groups open United States |
| Starflex vs medical treatment | | | |
| CLOSURE I, 2010 <i>unpublished</i> [NCT00201461] n=447/462 follow-up: 2 years | patent foramen ovale closure using the Starflex device versus best medical therapy: aspirin (325 mg daily) and/or warfarin (target INR = 2.5) | patients with a stroke and/or transient ischemic attack due to presumed paradoxical embolism through a patent foramen ovale | Parallel groups open US, Canada |

References

CLOSE, :

CryptoCard, :

REDUCE, :

CLOSURE I, 2010:

Furlan AJ, Reisman M, Massaro J, Mauri L, Adams H, Albers GW, Felberg R, Herrmann H, Kar S, Landzberg M, Raizner A, Wechsler L Study design of the CLOSURE I Trial: a prospective, multicenter, randomized, controlled trial to evaluate the safety and efficacy of the STARFlex septal closure system versus best medical therapy in patients with stroke or transient ischemic attack due to presumed paradoxical embolism through a patent foramen ovale. *Stroke* 2010;41:2872-83 [21051670] [10.1161/STROKEAHA.110.593376](https://doi.org/10.1161/STROKEAHA.110.593376)

Furlan AJ, Reisman M, Massaro J, Mauri L, Adams H, Albers GW, Felberg R, Herrmann H, Kar S, Landzberg M, Raizner A, Wechsler L Closure or medical therapy for cryptogenic stroke with patent foramen ovale. *N Engl J Med* 2012 Mar 15;366:991-9 [22417252] [10.1056/NEJMoa1009639](https://doi.org/10.1056/NEJMoa1009639)

2 About TrialResults-center.org

TrialResults-center is an innovative knowledge database that collects the results of RCTs and provides dynamic interactive systematic reviews and meta-analysis in the field of all major heart and vessels diseases.

The TrialResults-center database provides a unique view of the treatment efficacy based on all data provided directly from clinical trial results, offering a valuable alternative to personal bibliographic search, published meta-analysis, etc. Furthermore, it would allow comparing easily the various concurrent therapeutic for the same clinical condition.

Rigorous meta-analysis method is used to populate TrialResults-center: widespread search of published and non published trials, study selection using pre-specified criteria, data extraction using standard form.

TrialResults-center is continually updated on a weekly basis. We continually search all new results (whatever their publication channel) and these news results are immediately added to the database with a maximum of 1 week.

TrialResults-center is non-profit and self-funded.