

Botulinum Toxin Type A Blockade of the Sphenopalatine Ganglion in Treatment-refractory Chronic Cluster Headache

NCT03944876

Status	RECRUITING
Phase	Phase 3
Sponsor	Norwegian University of Science and Technology
Enrollment	112 participants

Key Eligibility Criteria

Inclusion (32)

- Informed and written consent.
- Male or female, 18-85 years of age
- Headache attacks fulfilling the International Classification of Headache Disorders (ICHD) III criteria for chronic cluster headache (CCH) 3.1.2.
- Dominant headache laterality with e 80% of cluster headache attacks on one side.
- Subject reports an average of e 4 cluster attacks/week on the side of their dominant headache laterality in the 3 months prior to inclusion and in the baseline period.

... and 27 more (see full listing online)

Exclusion (11)

- Subject has had a change in type, dosage or dose frequency of preventive headache medications e two weeks prior to baseline/screening or 5 half-lives, whichever is longer.
- Subject currently treated with occipital nerve stimulation, deep brain stimulation or other implantable device, that have changed parameters in the last month, or are unable to keep parameters stable throughout the study.
- Current or previous treatment with implanted medical devices targeting the SPG
- Subject has had a change in type, dosage or dose frequency of preventive headache medications during the baseline period, eg. prior to IMP administration.
- Non-responder to both oxygen and triptan.

... and 6 more (see full listing online)

Locations (5 total)

Praxisklinik Ulmenhof, Hamburg, Germany
Fondazione IRCCS Istituto Neurologico Carlo Besta (CBNI), Milan, Italy
St Olavs Hospital, Trondheim, Norway
... and 2 more locations

<https://clinicaltrials.gov/study/NCT03944876>

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