A Clinical Study on Recombinant Botulinum Toxin Type A (YY001) for Injection in The Treatment of Upper Limb Spasticity in Adults

NCT06783114

Status	RECRUITING
Phase	Phase 2, Phase 3
Sponsor	Chongqing Claruvis Pharmaceutical Co., Ltd.
Enrollment	254 participants

Key Eligibility Criteria

Inclusion (5)

- Age between 18 and 75 years old inclusive, at the time of signing the informed consent, regardless of gender.
- Subjects with unilateral hemiplegia due to stroke (with a time interval of e 3 months from stroke onset to randomized enrollment) exhibiting upper limb spasticity.
- Subjects with Disability Assessment Scale score of at least 2 on the Principal Target of Treatment (one of four functional domains: hygiene, dressing, limb position and pain).
- If taking oral antispasticity, the dosage must be stable for at least 1 month prior to randomized enrollment.
- If the study limb receives physical therapy or occupational therapy, the frequency, type, and intensity must be stable for at least 3 weeks prior to randomized enrollment.

Exclusion (9)

- History of allergy to any component of the experimental drugs.
- Previous use of any botulinum toxin within 6 months prior to randomized enrollment, or plan to use other botulinum toxins not specified in the study protocol during the study.
- Fixed contractures of the studied limb.
- Any medical condition that may increase the risk to the subject when using Botulinum Toxin Type A.
- Need for treatment with drugs that interfere with neuromuscular function during the study.

... and 4 more (see full listing online)

Locations (24 total)

Anhui Provincial Hospital, Hefei, Anhui, China
The Second People's Hospital of Hefei, Hefei, Anhui, China
Peking Union Medical College Hospital, Beijing, Beijing Municipality, China
... and 21 more locations