

MEIN/06/FRO-PP/002

A double-blind, cross-over patient preference study of frovatriptan versus rizatriptan for the acute treatment of migraine

This study has completed the enrolment of patients

Sponsor: Menarini International Operations Luxembourg S. A.

Intervention: Frovatriptan 2.5 mg by oral route, one up to two doses per episode per day. Control product: Rizatriptan 10 mg by oral route, one up to two doses per episode per day

Indication: Migraine with or without aura according to the IHS criteria

This study is designed to evaluate which drug the patient prefer for the treatment of their migraine attacks

Study type & design: Phase IV, randomised, double-blind, cross-over, active-drug controlled study.

Each patient will receive the two study treatments in sequence, being the sequence determined by randomisation. After having treated 3 episodes of migraine in not more than 3 months with the first treatment, the patient will switch to the other treatment. After having treated 3 episodes of migraine in not more than 3 months with the second treatment, the patient will indicate the preference for the first or second treatment, on a 10-cm visual analogue scale centred on 0 (no preference), with the strongest preference for either treatment set at ± 5 cm.

The patients' participation time to the study will thus be not in excess than 6 months.

Main criteria for inclusion:

Consenting ambulant male or non-pregnant female patients

Age ≥ 18 and ≤ 65 years

With history of migraine with or without aura according to the IHS criteria

With at least one but not more than six episodes per month during the last 6 months

Main criteria for exclusion:

History suggestive of ischaemic heart disease or any atherosclerotic disease indicating an increased risk of coronary ischaemia

Symptomatic Wolff-Parkinson-White syndrome or cardiac arrhythmias associated with other cardiac accessori

Conduction pathway disorders

History of stroke or transient ischaemic attack (TIA)

Uncontrolled hypertension

History of basilar, hemiplegic or ophthalmoplegic migraine;

Severe liver impairment (i.e., Child-Pugh score ≥ 7);

Severe renal impairment (i.e., CrCl < 26 ml/min), renal disease, or renal failure;