

MEIN/06/FRO-PP/001

A double-blind, cross-over patient preference study of frovatriptan versus zolmitriptan 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: Zolmitriptan 2.5mg 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.

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

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 accessory 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;

More than six days of tension-type headache