

LUMI/06/FRO-MIG/001

A patient preference study of frovatriptan versus rizatriptan for the acute treatment of migraine

This study has completed the enrolment of patients

Sponsor: Istituto Luso Farmaco d'Italia S.p.A.

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

Indication: Migraine with or without aura

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

Study type & design: Phase IV, multicentre, randomised, double-blind, active drug-controlled study of patient's preference in cross-over

Main criteria for inclusion:

Consenting ambulant male or non-pregnant female patients

Age ≥ 18 and ≤ 65 years

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 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 C);

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

More than six days of tension-type headache