

LUMI/06/FRO-MIG/002

A patient preference study of Frovatriptan versus Zolmitriptan for the acute treatment of migraine

This study is currently recruiting 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/zolmitriptan 2.5 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, double-dummy, 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

With history of migraine with or without aura according to the IHS criteria, with at least one episode 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;

known or suspected intolerance of, or hypersensitivity or contraindications to any component of the trial medications;