

GUI/06/FRO-PP/002

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

This study has completed the enrolment of patients

Sponsor: Laboratori Guidotti S.p.A.

Intervention: Frovatriptan 2.5 mg o.d. vs Almotriptan 12.5 mg o.d.

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

This study is designed to evaluate the subjective patient's preference for either study medication after having tested both Frovatriptan and Almotriptan on a number of between 1 and 3 attacks of migraine in a maximum period of 3 months. This will be evaluated independently in the two sequence subgroups

Study type & design: A double-blind, cross-over patient preference study of Frovatriptan versus Almotriptan for the acute treatment of migraine – Phase IV.

Main criteria for inclusion:

Ambulant male or non pregnant female subject

≥18 and ≤ 65 years of age at the randomisation visit

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

Having experienced an average of at least one but not more than six migraine attacks per month for 6 months prior to entry into the study

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