

A Efficacy and Safety Study of Ranibizumab 10mg/ml Injection (Incepta) in Patients With Diabetic Macular Edema

NCT06305416

Status	RECRUITING
Phase	Phase 3
Sponsor	Incepta Pharmaceuticals Ltd
Enrollment	70 participants

Key Eligibility Criteria

Inclusion (8)

- Ages Eligible for Study: e 18 Years
 - Ability to provide written informed consent and comply with study assessments for the full duration of the study
 - Diagnosis of diabetes mellitus (type 1 or 2). Any one of the following will be considered to be sufficient evidence that diabetes is present: Laboratory reports that prove DM of patient or current regular use of insulin for treatment of diabetes or current regular use of oral anti-hyperglycemic agent for the treatment of diabetes.
 - Clinical evidence of retinal thickening due to macular edema involving the center of the macula (can be associated with diabetic retinopathy)
 - Central diabetic macular edema present on clinical examination and OCT testing with central 1mm sub field thickness greater than 300 microns as measured on -OCT
- ... and 3 more (see full listing online)

Exclusion (16)

- Prior treatment with any Intravitreal drug, Bevacizumab, verteporfin or photodynamic therapy (except for extra foveal laser photocoagulation) in the study eye within past 3 months before study entry
 - Laser photocoagulation in the study eye within 1 month before study entry
 - Participation in another ocular investigation or trial simultaneously
 - Pregnancy (positive pregnancy test) or known to be pregnant; also pre-menopausal women not using adequate contraception.
 - Blood pressure \geq 160/100 mmHg (systolic above 160 or diastolic above 100) and Random Blood Sugar (RBS) \geq 12 mmol/L and/or HbA1c \geq 7.5%
- ... and 11 more (see full listing online)

Locations (1 total)

Bangladesh Eye Hospital & Institute, Dhaka, Bangladesh