

Implantation of a new intraocular lens for patients who require a new lens

Submission date 23/06/2021	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 29/06/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 12/04/2022	Condition category Eye Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Due to trauma or surgery, the natural or artificial intraocular lens may dislocate causing vision loss. The aim of the study is to determine the efficacy of the implant of a new intraocular lens to restore vision in these patients.

Who can participate?

Patients affected by aphakia or IOL dislocation

What does the study involve?

This study involves surgery to remove the luxated lens from the eye and implant an artificial intraocular lens to restore vision.

What are the possible benefits and risks of participating?

Possible benefits are an increase in vision and the reduction of the risk of further visual loss. The possible risks are the development of surgical complications possibly leading to further vision loss or to the need for further surgery.

Where is the study run from?

Morgagni Pierantoni Hospital (Italy)

When is the study starting and how long is it expected to run for?

June 2017 to November 2020

Who is funding the study?

Investigator initiated and funded

Who is the main contact?

Dr Edoardo Abed
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Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers**Clinical Trials Information System (CTIS)**

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

Nil known

Study information**Scientific Title**

One year outcomes and stability of a novel scleral anchored intraocular lens

Acronym

NSAIL

Study objectives

To assess 1-year outcomes and stability of a novel scleral anchored intraocular lens.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The study does not require ethics approval since the treatment protocol is already approved. Furthermore, no patient identifiable data were reported in the study.

Study design

Interventional non-masked study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Aphakia

Interventions

The study is a single arm trial. All patients underwent surgery consisting of vitrectomy, removal of dislocated lens and implantation of scleral fixation intraocular lens at baseline. Postoperative follow-up extended until 12 months after surgery.

Intervention Type

Procedure/Surgery

Primary outcome(s)

Visual acuity was measured in decimal Snellen units and then converted in Logarithm of minimum angle resolution (LogMAR) for statistical purposes assessed at baseline and at 1,3,6 and 12 months follow up

Key secondary outcome(s)

Assessed at baseline and at 1,3,6 and 12 months follow up

1. IOL stability was assessed comparing the angle, in degrees, between IOL optic and posterior iris plane.
2. Complications assessed using patient records

Completion date

30/11/2020

Eligibility

Key inclusion criteria

Postoperative or posttraumatic aphakia or late dislocation of IOL and or capsular bag

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Senior

Sex

All

Total final enrolment

60

Key exclusion criteria

1. Corneal opacities
2. Visually significant macular diseases

3. Retinal detachment
4. Optic disk atrophy
5. Advanced glaucoma
6. Any other ocular condition that was likely to compromise the functional outcome

Date of first enrolment

01/11/2017

Date of final enrolment

30/11/2019

Locations

Countries of recruitment

Italy

San Marino

Study participating centre

Morgagni Pierantoni Hospital

Department of Ophthalmology

Via Carlo Forlanini, 34

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Italy

47121

Study participating centre

San Marino State Hospital

Department of Ophthalmology

Via Vittorio Scialoja, 40

Republic of San Marino

San Marino

47893

Sponsor information

Organisation

Ospedale G.B. Morgagni - L.Pierantoni

ROR

<https://ror.org/03jd4q354>

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository.

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		26/08/2021	12/04/2022	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes