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

Submission date	Recruitment status	[_] Prospectively registered
23/06/2021	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
29/06/2021	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
12/04/2022	Eye Diseases	

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

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

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 measure
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

Secondary outcome measures
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

Overall study start date
01/06/2017

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

Age group

Senior

Sex
Both

Target number of participants
60

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
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Study participating centre
San Marino State Hospital
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Sponsor information

Organisation
Ospedale G.B. Morgagni - L.Pierantoni

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Sponsor type
Hospital/treatment centre

Website
http://www.ausl.fo.it/AziendaUSLdellaRomagnaForl%C3%AC/Ospedali/Unit%C3%A0Operative/tabid/211/Default.aspx

ROR
https://ror.org/03jd4q354

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a impacted peer-reviewed journal.

Intention to publish date
30/10/2021

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