India Glaucoma Outcomes and Treatment Trial

Submission date Recruitment status Prospectively registered 11/10/2005 No longer recruiting [] Protocol [] Statistical analysis plan Registration date Overall study status 30/03/2006 Completed [X] Results [] Individual participant data Last Edited Condition category 11/01/2021 **Eve Diseases**

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers N/A

Study information

Scientific Title

India Glaucoma Outcomes and Treatment Trial

Acronym

INGOTT

Study objectives

Surgery will be more effective than medicines in controlling glaucoma in India

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved by the Internal Review Boards at the Johns Hopkins University, Baltimore, USA and the Aravind Eye Hospital in India

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Glaucoma

Interventions

Medicine (timolol, latanaprost and brimonidine) versus surgery

Intervention Type

Procedure/Surgery

Primary outcome measure

- 1. Intraocular pressure
- 2. Visual acuity
- 3. Quality of life

Secondary outcome measures

Cataract grade

Overall study start date

Completion date

01/01/2007

Eligibility

Key inclusion criteria

Glaucoma patients over the age of 30 years in India

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

700

Total final enrolment

398

Key exclusion criteria

- 1. Previous surgery
- 2. Intraocular pressure (IOP) >35

Date of first enrolment

01/01/2003

Date of final enrolment

01/01/2007

Locations

Countries of recruitment

India

United States of America

Study participating centre

Wilmer 120

Baltimore United States of America 21287

Sponsor information

Organisation

Pfizer Inc. (USA)

Sponsor details

Corporate Headquarters New York United States of America 20001

Sponsor type

Industry

ROR

https://ror.org/01xdqrp08

Funder(s)

Funder type

Industry

Funder Name

Pfizer Inc.

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2012	11/01/2021	Yes	No