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Multicenter Uveitis Steroid Treatment Trial

Submission date	Recruitment status	[_] Prospectively registered
13/08/2007	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
17/08/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
26/11/2018	Eye Diseases	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.musttrial.org

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00132691

Secondary identifying numbers
N/A

Study information

Scientific Title
Multicenter Uveitis Steroid Treatment Trial

Acronym
MUST

Study objectives
Uveitis refers to several ocular disorders characterised by intraocular inflammation, which in the aggregate are a major cause of visual loss and blindness in the United States. Intermediate uveitis, posterior uveitis, and panuveitis are generally the more severe forms of uveitis, with the highest risk of vision loss, often requiring long-term systemic treatment.

1. Patients randomised to implant therapy will have better visual outcomes.
2. Patients randomised to implant therapy will have improved control of uveitis, a decreased rate of posterior segment structural complications of the uveitis (such as cystoid macular edema and epiretinal membranes), and an increased rate of corticosteroid-induced ocular complications, such as cataracts, ocular hypertension, and glaucoma.
3. Patients randomised to systemic therapy will have a higher rate of systemic complications, such as diabetes, hypertension, and osteoporosis.
4. Improved visual outcomes and the absence of systemic corticosteroid complications (and the additional treatments needed to combat them) will result in a better quality of life for patients randomised to implant therapy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Johns Hopkins Bloomberg School of Public Health Institutional Review Board (formerly known as Johns Hopkins Bloomberg School of Public Health Committee on Human Research), FDA# 00000287 (IRB ref: H.34.04.04.07.B1)
1. Protocol version 1.1, approved on the 18/05/2005
2. Protocol version 3.3, approved on the 03/09/2008
3. Protocol version 3.4, approved on the 13/08/2009

Study design
Open-label parallel-assignment randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Uveitis

Interventions
Intervention group: fluocinolone acetonide intraocular implant
Control group: oral corticosteroid with immunosuppressive agents as needed

The fluocinolone acetonide intraocular implant is a surgically implanted reservoir of corticosteroid designed to last approximately 2.5 years in order to provide long-term control of uveitis.

Total duration of follow-up: Minimum of 2 years (patients enrolled early in the study will be followed for up to 5 years)

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Fluocinolone acetonide, corticosteroid, immunosuppressive agents

Primary outcome measure
Change in best-corrected visual acuity as measured by a logarithmic chart (measured at every study visit). Total duration of follow-up: 2 years

Secondary outcome measures
1. Occurrence of ocular complications
2. Occurrence of systemic complications
3. Control of uveitis
4. Quality of life at baseline and 6 months, assessed using the 25-item National Eye Institute Visual Function Questionnaire (NEI VFQ-25) and the 36-item Short Form health survey (SF-36)
5. Mortality. Total duration of follow-up: 2 years.

The following tests will also be carreid out to assess the outcomes 1-3 above:
a. Eye exam/blood draw (laboratory) at every study visit
b. Visual field testing at baseline and yearly thereafter

Overall study start date
01/12/2005

Completion date
31/12/2011

Eligibility

Key inclusion criteria

1. Age 13 years or older
2. Best-corrected visual acuity of hand motions or better in at least one eye with uveitis
3. Intraocular pressure 24 mmHg or less in all eyes with uveitis

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
250

Key exclusion criteria
1. Inadequately controlled diabetes
2. Uncontrolled glaucoma
3. Advanced glaucomatous optic nerve injury
4. A history of scleritis; presence of an ocular toxoplasmosis scar
5. HIV infection or other immunodeficiency disease for which corticosteroid therapy would be contraindicated according to best medical judgment

Date of first enrolment
01/12/2005

Date of final enrolment
31/12/2011

Locations

Countries of recruitment
Australia

United Kingdom

United States of America

Study participating centre
Mount Sinai School of Medicine
New York
United States of America
10029-6584

Sponsor information

Organisation
The Multicenter Uveitis Steroid Treatment Trial (MUST) Coordinating Center (USA)

Sponsor details
c/o Janet Holbrook
Johns Hopkins Center for Clinical Trials
Bloomberg School of Public Health
911 South Ann Street
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Sponsor type
Other

Funder(s)

Funder type
Government

Funder Name
National Eye Institute

Alternative Name(s)
Instituto Nacional del Ojo, NIH/National Eye Institute, NEI

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United States of America

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?
Basic results				No	No
Protocol article	protocol	01/04/2010		Yes	No
Results article	results	01/11/2015		Yes	No