

Multicenter Uveitis Steroid Treatment Trial

Submission date 13/08/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 17/08/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 26/11/2018	Condition category Eye Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Study website

<http://www.musttrial.org>

Contact information

Type(s)

Scientific

Contact name

Dr Douglas Jabs

Contact details

Mount Sinai School of Medicine
Department of Ophthalmology
One Gustave L. Levy Place
Box 1183
New York
United States of America
10029-6584

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 carried 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
Baltimore
Maryland
United States of America
21231

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