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Adjunctive steroid combination in ocular trauma study

Submission date	Recruitment status	[X] Prospectively registered
05/09/2014	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[X] Statistical analysis plan
05/09/2014	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
16/10/2023	Eye Diseases	

Plain English summary of protocol

Background and study aims
Trauma is an important cause of visual impairment and blindness worldwide and a leading cause of blindness in young adult males. Globally it has been estimated that 1.6 million people are blind as a result of ocular trauma (eye injuries) with 2.3 million suffering bilateral low vision (i.e., affecting both eyes). Eye trauma is the most common cause of one-sided blindness in the world today with up to 19 million with one-sided blindness or low vision. It is estimated that almost one million people in the United States live with trauma-related visual loss. Eye trauma has a burden on society and cost implications patients with eye injuries lose a mean of 70 days of work. In the United States work-related eye injuries cost over $300 million per year. The study aims to see if an adjunctive triamcinolone acetonide, given at the time of surgery, can improve the outcome of surgery for open globe eye trauma.

Who can participate?
Adults aged over 18 with an open globe eye injury undergoing vitrectomy surgery.

What does the study involve?
Participants will be randomly divided into two equal groups. The study group will receive standard care and the addition of the steroid medication, and the control group will receive standard care alone. Following surgery, there will be the usual examinations and participants will be followed up for 6 months after surgery.

What are the possible benefits and risks of participating?
The risk is no higher than the risk of standard medical care. Triamcinolone acetonide has been used off label in clinical practice for many years by experienced specialists. It has been seen as very safe. The most common important side effect seen so far is elevated pressure in the eye (intraocular pressure).

Where is the study run from?
Moorfields Eye Hospital (UK)

When is study starting and how long is it expected to run for?
October 2014 to August 2017

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
R&D Office Moorfields Eye Hospital NHS Foundation Trust

Contact information

Type(s)
Scientific

Contact name
Dr R&D Office

Contact details
Moorfields Eye Hospital NHS Foundation Trust
162 City Road
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Additional identifiers

ClinicalTrials.gov (NCT)
NCT02873026

Clinical Trials Information System (CTIS)
2014-002193-37

Protocol serial number
HTA 12/35/64

Study information

Scientific Title
A phase III multi-centre double-masked randomised controlled trial of adjunctive intraocular and periocular steroid (triamcinolone acetonide) versus standard treatment in eyes undergoing vitreoretinal surgery for open globe trauma; the Adjunctive Steroid Combination in Ocular Trauma (ASCOT) trial

Acronym
ASCOT

Study objectives
The study aims to test the hypothesis that adjunctive triamcinolone acetonide, given at the time of surgery, can improve the outcome of vitreoretinal surgery for open-globe ocular trauma.

More details can be found at: http://www.nets.nihr.ac.uk/projects/hta/123564
Protocol can be found at: http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0009/166509/PRO-12-35-64.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
London - Central Research Ethics Committee, 05/09/2014, ref: 14/LO/1428

Primary study design
Interventional

Study design
Randomized; Interventional; Design type: Treatment

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: Ophthalmology; Subtopic: Eye (all Subtopics); Disease: Ophthalmology

Interventions
The study will involve 300 participants recruited at vitroretinal surgery centres at 20 sites across England and Scotland. Participation will be followed 6 months following surgery.

Treatment arm: the following medications are only administered to participants allocated to the treatment arm of the study:
1. 4 mg/0.1 ml triamcinolone acetonide administered into the vitreous cavity by the operating surgeon at the end of the procedure
2. 40 mg/1 ml of triamcinolone acetonide administered into the subtenons space at the end of the procedure (where subtenons anaesthesia is used for postoperative analgesia, surgeons will be requested to administer the local anaesthetic mid-procedure i.e. not concurrently)

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Triamcinolone acetonide

Primary outcome(s)
Primary outcome measure as of 01/06/2016:
The proportion of patients with an improvement from baseline to 6 months of at least 10 on the corrected visual acuity in the study eye (total ETDRS letter score measured at 4 metres and 1 metre).

Original primary outcome measures:
1. Corrected visual acuity score (ETDRS letter score) at 6 months after initial study surgery
2. Proportion of patients with an improvement from baseline to 6 months of at least 10 on the corrected visual acuity (ETDRS letter score)

Key secondary outcome(s)

Secondary outcome measures as of 01/06/2016:
1. Total EDTRS score in the study eye at the 6 months follow up appointment
2. The proportion of patients in whom retinal detachment with PVR occurs at any timepoint within 6 months of the study vitrectomy
3. The proportion of patients in whom stable complete retinal reattachment (without internal tamponade present) is achieved at 6 months post study vitrectomy
4. The proportion of patients in whom stable macular retinal reattachment (without internal tamponade present) is achieved at 6 months post study vitrectomy
5. The proportion of patients in whom a tractional retinal detachment occurs at any timepoint within 6 months of the study vitrectomy
6. The number of operations to achieve stable retinal reattachment (either complete or macula) at 6 months after the study vitrectomy
7. The proportion of patients who suffer hypotony (<6mm Hg) at any timepoint within 6 months of the study vitrectomy
8. The proportion of patients who suffer raised intraocular pressure (>25mm Hg) at any timepoint within 6 months of the study vitrectomy
9. The proportion of patients who develop macula pucker by 3 and 6 months and/or require macular pucker surgery at any timepoint within 6 months of the study vitrectomy
9. Quality of Life is measured using:
9.1. Client Service Receipt Inventory (CSRI) at baseline (1 page), 3 and 6 months (2 pages). At baseline, participants will be asked to recall service use in the last 4 weeks and at 3 and 6 months participants will be asked to recall their service use for the previous 3 months
9.2. EQ-5D-5 at baseline, 3 and 6 month
9.3. VFQ-25 at baseline, 3 and 6 month

Original secondary outcome measures:
1. The proportion of patients in whom retinal detachment with PVR occurs at any timepoint within 6 months of the study vitrectomy
2. The proportion of patients in whom stable complete retinal reattachment (without internal tamponade present) is achieved at 6 months post study vitrectomy
3. The proportion of patients in whom stable macular retinal reattachment (without internal tamponade present) is achieved at 6 months post study vitrectomy
4. The proportion of patients in whom a tractional retinal detachment occurs at any timepoint within 6 months of the study vitrectomy
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7. The proportion of patients who suffer raised intraocular pressure (>25 mmHg) at any timepoint within 6 months of the study vitrectomy
8. The proportion of patients who develop macula pucker by 3 and 6 months and/or require macular pucker surgery at any timepoint within 6 months of the study vitrectomy
9. Quality of Life:
9.1. Client Service Receipt Inventory (CSRI). Primary and secondary health and social care service use will be recorded using a brief CSRI created for the study. The CSRI will be recorded at

baseline (1 page), 3 and 6 months (2 pages). At baseline, participants will be asked to recall service use in the last 4 weeks and at 3 and 6 months participants will be asked to recall their service use for the previous 3 months.
9.2. EQ-5D-5. The EQ-5D is a generic, preference-based, health-related quality of life (HRQoL) measure. It consists of two parts: a five-item questionnaire and a visual analogue scale (EQ-VAS). The EQ-5D-5L questionnaire is scored between -0.59 and 1, with 1 meaning full HRQoL. Currently, no scoring algorithm exists to convert EQ-5D-5L responses into an index score, therefore we will use an interim scoring algorithm that maps responses onto the EQ-5D-3L. The EQ-VAS is a thermometer scored between 0-100, with respondents asked to mark their current HRQoL level.
9.3. VFQ-25. The VFQ25 measures vision-related QoL. Items are converted into a score between 0-100, where 100 represents full capability, and then the subscales are averaged to produce the composite score.

Completion date
01/12/2020

Eligibility

Key inclusion criteria
1. Adult subjects (aged 18 years or over at the time of enrolment)
2. Full thickness, open-globe ocular trauma undergoing vitrectomy
3. Ability to give written informed consent
4. Willingness to accept randomization and attend follow-up for 6 months.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Children (age less than 18 years old at time of enrollment)
2. Pre-existing uncontrolled uveitis (this does not include patients whose uveitis is secondary to their injury or retinal detachment)
3. Definitive diagnosis of previous steroid-induced glaucoma (this does not include patients in whom a query of previous steroid-induced raised IOP has been postulated)
4. Pregnant or breastfeeding females. Females of childbearing potential must be willing to use an effective method of contraception (hormonal or barrier method of birth control; true abstinence) from the time consent is signed until 6 weeks after completion of the trial. Females of childbearing potential must have a negative urinary pregnancy test within 7 days prior to

being registered for trial treatment (subjects are considered not of childbearing potential if they are permanently sterile [i.e. they have undergone a hysterectomy, bilateral tubal occlusion, or bilateral salpingectomy or they are postmenopausal]).
5. Allergy or previous known adverse reaction to triamcinolone acetonide
6. Inability to attend regular follow up.
7. Unable to give written informed consent.
8. Current or planned systemic corticosteroid use of a dose above physiological levels (e.g. >10 mg prednisolone)

Date of first enrolment
01/10/2014

Date of final enrolment
30/08/2017

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Moorfields Eye Hospital
162 City Road
London
United Kingdom
EC1V 2PD

Sponsor information

Organisation
Moorfields Eye Hospital NHS Foundation Trust (UK)

ROR
https://ror.org/03zaddr67

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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-publicly available repository. As this is a clinical trial of an investigational medicinal product (CTIMP) the data will be on Clinicaltrials.gov and EUDRACT.

Previous publication and dissemination plan:
The protocol and statistical analysis plan have both been submitted for publication and are currently under review.

IPD sharing plan summary
Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	protocol	01/07/2023	16/10/2023	Yes	No
Protocol article		22/07/2016		Yes	No
Basic results	statistical analysis plan	01/12/2021	16/06/2022	No	No
HRA research summary			28/06/2023	No	No
Statistical Analysis Plan		02/08/2016		No	No