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A randomised trial of pulsed intravenous methylprednisolone for severe ocular pemphigoid

Submission date	Recruitment status	[ ] Prospectively registered
12/12/2006	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
29/01/2007	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
15/06/2017	Skin and Connective Tissue Diseases	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
SAWV1003; RTF1226

Study information

Scientific Title
A randomised trial of pulsed IntraVenous MethylPrednisolone for severe ocular pemphigoid

Acronym
IVMP

Study objectives
To test the hypothesis that intravenous methylprednisolone induces more rapid control of ocular inflammation in patients with severe ocular pemphigoid (an intractable condition of the front surface of the eye which causes blindness by inflammation and irreversible scarring).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Research Ethics Committee, 20/09/2005, ref: 05/Q1604/126

Study design
Randomised controlled single-masked clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Ocular mucous membrane pemphigoid

Interventions
Intervention:
Intravenous methylprednisolone therapy 1 g in 250 ml of 0.9% saline daily administered over 30 minutes for three consecutive days, followed by a 6-233k tapering course of oral prednisolone 1 mg/kg/day, along with commencement of oral cyclophosphamide 1 - 2 mg/kg/day.

Control treatment:
Six and a half week course of oral prednisolone 1 mg/kg/day along with commencement of oral cyclophosphamide 1 - 2 mg/kg/day.

Intervention Type

Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Methylprednisolone

Primary outcome measure
Proportion of eyes achieving control of inflammation to grade 0 (nil) or grade 1 (minimal) at six weeks. This disease is not symmetric and responses between eyes can be very different.

Secondary outcome measures
Proportion of patients achieving, at six weeks, a four-fold reduction in titre of circulating antibasement membrane antibodies.

Overall study start date
20/01/2006

Completion date
20/01/2008

Eligibility

Key inclusion criteria
1. Patients with clinical features consistent with ocular mucous membrane pemphigoid
2. Patients with bilateral or unilateral moderate (grade 3) or severe (grade 4) ocular inflammation, with or without limbitis (i.e. oedema and increased vascularity along the limbus)
3. Patients may already be receiving non-cyclophosphamide immunosuppression

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
20

Key exclusion criteria
1. Patients currently receiving cyclophosphamide
2. Patients with other causes of progressive conjunctival scarring (drug-induced pemphigoid with negative direct immunofluorescence biopsy, atopic keratoconjunctivitis, Sjogrens syndrome, Stevens Johnson syndrome, chemical injury)
3. Active secondary malignancy
4. HIuman immunodeficiency virus (HIV) infection
5. Pregnancy or breastfeeding

Date of first enrolment
20/01/2006

Date of final enrolment
20/01/2008

Locations

Countries of recruitment
England

United Kingdom

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

Sponsor information

Organisation
Moorfields Eye Hospital NHS Foundation Trust (UK)

Sponsor details
162 City Road
London
England
United Kingdom
EC1V 2PD

Sponsor type
Hospital/treatment centre

Website
http://www.moorfields.nhs.uk/Home

ROR
https://ror.org/03zaddr67

Funder(s)

Funder type

Hospital/treatment centre

Funder Name
Special Trustees of Moorfields Eye Hospital (UK)

Funder Name
University College London Graduate School Research Scholarship (UK)

Funder Name
Action Medical Research (UK) (Ref: RTF1226)

Alternative Name(s)
actionmedres, action medical research for children, AMR

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

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