

A randomised trial of pulsed intravenous methylprednisolone for severe ocular pemphigoid

Submission date 12/12/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 29/01/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 15/06/2017	Condition category Skin and Connective Tissue Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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. Human 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