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# A randomised trial of pulsed intravenous methylprednisolone for severe ocular pemphigoid

**Submission date**
12/12/2006

**Recruitment status**
No longer recruiting

**Registration date**
29/01/2007

**Overall study status**
Completed

**Last Edited**
15/06/2017

**Condition category**
Skin and Connective Tissue Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

**Contact name**
Miss Valerie Saw

**Contact details**
Imperial College NHS Trust & UCL Institute of Ophthalmology
London
United Kingdom
EC1V 2PD
+44 7875 483586
v.saw@ucl.ac.uk

## Additional identifiers

**Protocol serial number**
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

## Study type(s)
Treatment

## 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(s)
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.

## Key secondary outcome(s))

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

### 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

### Healthy volunteers allowed
No

### Age group
Not Specified

### Sex

### 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
United Kingdom

England

### Study participating centre

**Moorfields Eye Hospital**
London
United Kingdom
EC1V 2PD

# Sponsor information

**Organisation**
Moorfields Eye Hospital NHS Foundation Trust (UK)

**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)**
action medical research for children, actionmedres, The National Fund for Research into Crippling Diseases, AMR

**Funding Body Type**
Private sector organisation

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

**Location**
United Kingdom

# Results and Publications

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary