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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

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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

Primary study design
Interventional

Study design
Randomised controlled single-masked clinical trial

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