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Relapse ESCalation treatment trial in Optic Neuritis (RESCON)

Submission date
06/10/2013

Recruitment status
Stopped

Registration date
06/08/2014

Overall study status
Stopped

Last Edited
11/05/2021

Condition category
Eye Diseases

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

Plain English summary of protocol

Background and study aims
Plasma exchange (PE) is a procedure where the plasma of the blood is replaced by another component called plasma substitute. It has been used as an escalation treatment and after failure of high doses of steroids in the treatment of optic neuritis (inflammation of the optic nerve). However, until now only one study has evaluated PE for the treatment of MS relapses. The current experience in treating optic neuritis that does not respond to steroids with PE is limited. This study will be the first rigorous clinical study in severe optic neuritis that does not respond to steroids, and will provide evidence regarding the effectiveness of PE in optic neuritis.

Who can participate?
Adult patients with optic neuritis that did not respond to steroid treatment and an overall duration of symptoms of less than 4 weeks.

What does the study involve?
Patients will be randomly allocated to two different treatment options: five cycles of plasma exchange or methylprednisolone (a very high dosage of steroid) for five consecutive days.

What are the possible benefits and risks of participating?
Both the treatment options in this study are established therapies so we do not expect to observe unpredictable risks or side effects. If patients in the steroid treatment arm do not respond well, we offer the rescue treatment with plasma exchange 8 weeks after the steroid treatment.

Where is the study run from?
The study will be conducted in five centres in Germany (Hamburg, Heidelberg, Hannover, Berlin and Düsseldorf). The lead centre will be Hamburg.

When is the study starting and how long is it expected to run for?
The study started in October 2013 and will last for about 2 years.

Who is funding the study?
The Federal Ministry of Education and Research (Bundesministerium für Bildung und Forschung) (BMBF) (Germany).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Clinical Trials Information System (CTIS)
2012-004807-10

Protocol serial number
inims-004

Study information

Scientific Title
Relapse ESCalation treatment trial in Optic Neuritis (RESCON): a multi-centre randomised controlled trial to study the effectiveness of plasma exchange (PE) as an escalation treatment strategy in steroid-unresponsive optic neuritis

Acronym
RESCON

Study objectives
Primary objectives:
1. To gain further evidence for the efficacy of plasma exchange in steroid-unresponsive optic neuritis

2. To study new outcome tools for neuronal regeneration in the ON model via optical coherence tomography (OCT)

Secondary objectives:
1. To study MRI parameters in patients with steroid-unresponsive optic neuritis treated with plasma exchange (contrast-enhancement, T2-signal, edema and atrophy will be assessed as well as diffusion tensor imaging (DTI) at baseline, week 16 and 52)
2. To further study biomarkers for ON heterogeneity and neurodegeneration

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of Hamburg, 17/07/2013

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Steroid-unresponsive optic neuritis

Interventions
RCT in patients who suffer from severe optic neuritis without satisfying improvement after treatment with steroids.

Treatment arm 1: plasma exchange (PE)
PE will be performed every second day; altogether five exchanges are planned. Each procedure will last about 2-3 hours. After placing a central venous catheter in a jugular or subclavian vein the 1.5-fold plasma volume will be exchanged with the same volume of human albumin 5% or a combination of albumin and hemodilution by continuous-flow centrifugation using a cell separation device.

Treatment arm 2: ultrahigh-dose steroid treatment
Each day 2 g of methylprednisolone will be administered intravenously on five consecutive days.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Mean retina nerve fiber layer thickness in OCT at week 16 after treatment in comparison between groups

Key secondary outcome(s))
1. Treatment failure at week 2
2. Visual acuity measured at inclusion, week 2, 4, 8, 16, 52 after treatment
3. Visual evoked potential latency measured at inclusion, week 2, 4, 8, 16, 52 after treatment
4. MRI parameters at week 1, 2, 4, 16, 52

Completion date
10/10/2015

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
1. Optic neuritis with visual acuity < 0.7 at least 7 days after steroid treatment (3-5 x 1 g)
2. Duration of symptoms from onset < 4 weeks
3. Male and female, age: 18-60 years
4. Expanded Disability Status Scale (EDSS): 1.0 6.5
5. Clinically isolated syndrome (CIS), relapsing-remitting multiple sclerosis (RR-MS) or secondary progressive multiple sclerosis (SP-MS)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
60 years

Sex
All

Total final enrolment
9

Key exclusion criteria
1. Absence of evidence of inflammatory activity which is defined as a lack of inflammatory CSF signs (pleocytosis and/or OCBs) or a present MRI without at least two MS-typical lesions
2. Bilateral optic neuritis
3. Positive testing for aquaporin-4 antibodies
4. Current treatment with natalizumab
5. Patients with neuromyelitis optica

6. Pregnancy
7. Unwillingness or inability to comply with the requirements of this protocol including the presence of any condition (physical, mental, or social) that is likely to affect the patient returning for follow-up visits on schedule.
Patients with cognitive impairments who are unable to provide written, informed consent prior to any testing under this protocol.

Date of first enrolment
10/10/2013

Date of final enrolment
10/10/2015

Locations

Countries of recruitment
Germany

Study participating centre
Institute of Neuroimmunology and Clinical MS Research
Hamburg
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20246

Sponsor information

Organisation
University Medical Center Hamburg-Eppendorf (Universitätsklinikum Hamburg-Eppendorf) (Germany)

ROR
https://ror.org/01zgy1s35

Funder(s)

Funder type
Government

Funder Name
The Federal Ministry of Education and Research (Bundesministerium für Bildung und Forschung) (BMBF) (Germany)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes