

Clinical response to intravenous immunoglobulin inpatients with complex regional pain syndrome (CRPS)

Submission date 29/09/2006	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 29/09/2006	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 25/02/2010	Condition category Signs and Symptoms	☐ Individual participant data

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
N0263177713

Study information

Scientific Title

Randomised, double blinded, placebo controlled crossover trial to assess the clinical response to intravenous immunoglobulin in patients with complex regional pain syndrome (CRPS), and to ascertain pathogenic serum factors

Study objectives

To assess if intravenous immunoglobulin (IVIg) is more effective than saline in relieving pain from complex regional pain syndrome (CRPS), and to ascertain pathogenic serum factors in patients versus healthy controls.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Research Ethics of the National Hospital for Neurology and Neurosurgery gave approval on the 6th April 2005 (ref: 06/044)

Study design

Randomised double blinded placebo controlled crossover trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Complex regional pain syndrome (CRPS)

Interventions

1. Intravenous immunoglobulin (0.5 g/kg)
2. Placebo

Patients were given an infusion of one of the above on two consecutive days, then crossed-over to the other arm for one infusion given on two consecutive days, no less than 28 days after the original infusion. Follow up: 3 months.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Immunoglobulin

Primary outcome(s)

The average numeric rating scale pain value from day four to day 18 after infusions compared between IVIg and saline

Key secondary outcome(s)

1. The number of patients who found either treatment more effective
2. The global impression of change values between day four to day 18 after infusions compared between IVIG and saline

Completion date

01/08/2008

Eligibility

Key inclusion criteria

1. 16 patients from Pain Management aged 16 years and older, male and female
2. CRPS of between 6 and 30 months duration
3. Numeric rating scale pain score greater than 4

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

16 years

Sex

All

Key exclusion criteria

1. Pregnant or lactating women
2. IgA deficiency

Date of first enrolment

01/11/2005

Date of final enrolment

01/08/2008

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Pain Management Department
London
United Kingdom
WC1N 3BG

Sponsor information

Organisation

Record Provided by the NHSTCT Register - 2006 Update - Department of Health

Funder(s)

Funder type

Government

Funder Name

University College London Hospitals NHS Foundation Trust (UK)

Funder Name

University College London Hospitals (UCLH) Trustees (UK)

Funder Name

NHS R&D Support Funding (UK)

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?
Results article	results	02/02/2010		Yes	No