ISRCTN63918259 https://doi.org/10.1186/ISRCTN63918259

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

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

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

N0263177713

Study information

Scientific Title
Randomised, double blinded, placebo controlled crossover trial to assess the clinical response to intravenous immunoglobulin inpatients 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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

Secondary outcome measures
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

Overall study start date
01/11/2005

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

Age group
Adult

Lower age limit
16 Years

Sex
Both

Target number of participants
16

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
England

United Kingdom

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

Sponsor details
The Department of Health, Richmond House, 79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

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

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	02/02/2010		Yes	No