

ImmunoGlobulin administered SubCutaneously (SCIG) in Complex Regional Pain Syndrome (CRPS) over 12 months

Submission date 13/10/2010	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 10/03/2011	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 08/09/2014	Condition category Other	☐ 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

Clinical Trials Information System (CTIS)
2009-015242-30

Protocol serial number
2009-001

Study information

Scientific Title

An open study to compare the efficacy of ImmunoGlobulin administered SubCutaneoulsy (SCIG) with current best practice in patients with Complex Regional Pain Syndrome (CRPS)

Acronym

SCIG in CRPS

Study objectives

To ascertain the efficacy of repeated doses over one year of immune modulation treatment with a subcutaneous preparation of immunoglobulins (SCIG) in patients who had pain relief after a single-dose intravenous immunoglobulin treatment.

Please note that the participants of this trial have all taken part in a previous trial entitled: Clinical response to intravenous immunoglobulin in patients with complex regional pain syndrome (CRPS) (see <http://www.controlled-trials.com/ISRCTN63918259> for the ISRCTN record of this trial).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Joint UCL/UCLH Ethics Committees of Human Research (Committee A), 24/09/2009, ref: 09/H0714/47

Primary study design

Interventional

Study design

Open-label controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Chronic Regional Pain Syndrome

Interventions

There are two groups. One gets SCIG and usual care (we call it best medical care, BMC) the other gets BMC only. Treatment duration is 12 months with follow ups at 18 and 24 months.

The SCIG group receive: a priming dose at 1 g/kg of Sandoglobulin® NF Liquid or Privigen® (intravenously). A maintenance dose of 1 g/kg/month of Vivaglobulin is divided into weekly amounts and given subcutaneously. After 6 months the dose may be reduced 0.5 g/kg/month. After 3 months, if patients' relief is maintained the dose is further reduced by half to 0.25 g/kg/month for the remainder of the study (up to 12 months). Should patients experience increased pain following the dose reduction, the previous higher dose will be reinstated (0.5 or 1 g/kg/month).

BMC is recorded and monitored throughout. It is not possible to detail this as its dependent on patients' previous and current treatments but may include physiotherapy, occupational therapy, psychology, pain management programme.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Pain measured on a 0-10 Numerical Rating Scale. Changes in the mean pain score over a two-week period at baseline compared to mean pain score over a two-week period at the end of treatment.

Key secondary outcome(s)

1. Quantitative Sensory Testing (QST) values before versus after treatment and after a continuous period of treatment, including sensory thresholds and allodynia values.
2. 0-10 Numerical Rating Scale for Pain (NRS) assessed daily throughout the study
3. Questionnaire booklet: completed monthly throughout the study to assess pain-related functioning, mood, quality of life and illness perceptions using the following validated questionnaires:
 - 2.1. Brief Pain Inventory (BPI)
 - 2.2. EuroQol-5D
 - 2.3. Illness Perception Questionnaire (IPQ)
 - 2.4. Tampa Scale for Kinesophobia (TSK)
 - 2.5. Pain Catastrophising Scale (PCS)
 - 2.6. Perceived Adjustment to Chronic Illness Scale (PACIS) coping scale
 - 2.7. Hospital Anxiety and Depression Scale (HADS)

Completion date

01/08/2011

Eligibility

Key inclusion criteria

1. Intervention group:
 - 1.1. Diagnosis of CRPS according to the 'Bruehl' criteria
 - 1.2. Recruited from a previous RCT in London, responding better to intravenous immunoglobulin (IVIG) than normal saline
 - 1.3. At least a 24h average pain intensity of 6 over one week (one day of a lower pain intensity of 5 acceptable). Pain intensity must be judged as stable by the principal investigator (PI)
 - 1.4. Patients and matched controls should have used routine medications before enrollment including gabapentin and/or pregabalin, duloxetine and/or venlafaxine, a tricyclic antidepressant, lignocaine patches, both a strong and weak opioid in an appropriate dose without sufficient benefit.
 - 1.5. Patients who wish not to follow recommendations of the trial team as to receiving concomitant treatment according to best medical care will nevertheless be suitable for enrollment.
 - 1.6. Aged 18 years or over

2. Control group:

2.1. Selected from patients seen at the Walton Centre over the prior 18 months

2.2. Matched for:

2.2.1. Age $\pm$ 10 years

2.2.2. Sex

2.2.3. Average 24 h pain intensity and acute limb activity related pain intensity $\pm$ 2 points (but not below 5 on the NRS)

2.2.4. Disease duration $\pm$ 18 months

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. All patients (cases and controls):

1.1. Have evidence of significant organic disease on history or physical examination, which may be severe enough to prevent the patient from being able to complete the study

1.2 Suffer from another severe chronic pain syndrome such as fibromyalgia which may in the judgement of principle investigator hinder the appropriate assessment of pain from CRPS

1.3 Have a history of abuse or are currently abusing alcohol or drugs [using DSMIV criteria]

1.4. Have a psychiatric disorder which may in the judgement of the site investigator interfere with successful study participation

1.5. Are unwilling or not able to complete daily diaries

1.6. Do not understand the psychological questionnaires because appropriate validated translations into the patient's language are not available

2. Intervention group:

2.1. IgA serum levels within normal ranges. All patients in the SCIG group have already been tested for their IgA serum levels which were normal in all cases.

2.2. Patients with progressive renal failure and any patient requiring IVIG for another disorder

2.3. Treatment will be deferred in patients with an infection such as cold, flu or infected pressure sores until the infection has resolved because IG is contraindicated in cases of untreated bacterial infection

2.4. For the following patients in the SCIG group suitability for participation needs to be discussed with a specialist consultant:

2.4.1. Patients with compensated renal failure, patients suffering from epilepsy

2.4.2. Patients with a history of stroke or myocardial infarction

2.4.3. Patients with a known procoagulatory or bloodhyperviscosity disorder

2.4.4. Patients on loop diuretics

2.4.5. Patients with cancer other than basal cell carcinoma within the last 5 years. Those patients

who have received definite treatment, such as curative surgery, with no known recurrence can be included without further discussion

Date of first enrolment

01/08/2010

Date of final enrolment

01/08/2011

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Pain Relief

Liverpool

United Kingdom

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Sponsor information

Organisation

The Walton Centre NHS Foundation Trust (UK)

ROR

<https://ror.org/05cvxat96>

Funder(s)

Funder type

Industry

Funder Name

CSL Behring (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	01/11/2013		Yes	No
HRA research summary			28/06/2023	No	No