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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 [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 10/03/2011	**Overall study status** Completed	
Last Edited 08/09/2014	**Condition category** Other	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Andreas Goebel

Contact details
Pain Relief
Clincial Sciences Centre
The Walton Centre NHS Foundation Trust
Lower Lane
Liverpool
United Kingdom
L9 7LJ
andreasgoebel@rocketmail.com

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 inpatients 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

Study design
Open-label controlled trial

Primary study design
Interventional

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® (intraveneously). 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 Kinesaphobia (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, duloxetin and/or venlaflaxine, 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 +/10 years
2.2.2. Sex
2.2.3. Average 24 h pain intensity and acute limb activity related pain intensity +/2 points (but not below 5 on the NRS)
2.2.4. Disease duration +/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
L9 7LJ

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