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Human stress protein (immunoglobulin Binding Protein [BiP]) for the treatment of rheumatoid arthritis

Submission date	Recruitment status	[X] Prospectively registered
25/07/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
04/09/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
09/08/2016	Musculoskeletal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Gabriel Panayi

Contact details
Department of Rheumatology
Guy's Hospital
London
United Kingdom
SE1 9RT
-
gabriel.panayi@kcl.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
BiP-01

Study information

Scientific Title
Human stress protein (immunoglobulin Binding Protein [BiP]) for the treatment of rheumatoid arthritis: a randomised, placebo-controlled, single escalating dose trial

Study objectives
BiP will safely suppress inflammatory joint synovitis in patients with rheumatoid arthritis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Guy's and St Thomas's NHS Trust Hospital Ethics Board, 01/04/2008, ref: 07/H0802/114

Study design
Randomised placebo-controlled single escalating dose trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Rheumatoid arthritis

Interventions
This is a single escalating dose placebo-controlled randomised clinical trial of the efficacy of BiP administered intravenously for the treatment of patients with active rheumatoid arthritis who have failed methotrexate therapy.

There are four treatment groups. In each treatment group six patients will be randomly allocated to active treatment and two to placebo. Patients will receive only a single dose. Escalation to the next highest dose will only take place four weeks after safety evaluation from the last visit of the last patient in the previous group. The doses of BiP to be administered are 1, 2.5, 10 or 100 mg per patient. Patients will be monitored closely during the first 24 hours after infusion in a clinical research facility. They will thereafter be reviewed for safety and efficacy at weekly intervals up to four weeks.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Human stress protein (immunoglobulin Binding Protein [BiP])

Primary outcome measure
Safety: a close watch will be kept on side-effects and in particular serious adverse events. The side-effects will be monitored by a safety committee consisting of two rheumatologists with expertise in this area but who are in no way connected to the trial.

The primary and secondary endpoints will be measured prior to the intravenous infusion, at the end of 24 hours and weekly thereafter to the fourth week.

Secondary outcome measures
1. Clinical efficacy as measured by the American College of Rheumatology (ACR) 20, ACR 50 and ACR 70 response criteria and the European League Against Rheumatism Disease Activity Score (EULAR DAS28)
2. Immunological measurements of immune responses such as T-cell proliferation to tuberculin Purified Protein Derivative (PPD), Phytohaemagglutinin (PHA) and BiP; the development of regulatory T-cells; and cytokine production.

The primary and secondary endpoints will be measured prior to the intravenous infusion, at the end of 24 hours and weekly thereafter to the fourth week.

Overall study start date
01/09/2009

Completion date
01/12/2014

Eligibility

Key inclusion criteria
1. Active rheumatoid arthritis (RA)
2. Females aged 25 to 75 years

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants

Key exclusion criteria
1. Intercurrent serious disease
2. Malignancy
3. Pregnant/lactating

Date of first enrolment
01/09/2012

Date of final enrolment
01/08/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Guy's Hospital
London
United Kingdom
SE1 9RT

Sponsor information

Organisation
King's College London Enterprises (UK)

Sponsor details
Capital House
Guy's Hospital
London
England
United Kingdom
SE1 9RT
+44 (0)20 7188 5880
gabriel.panayi@kcl.ac.uk

Sponsor type
University/education

Website

http://www.kcl.ac.uk

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Industry

Funder Name
Immune Regulation Ltd (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	01/11/2016		Yes	No