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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

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Additional identifiers

Protocol serial number
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

Primary study design
Interventional

Study design
Randomised placebo-controlled single escalating dose trial

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s)
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.

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

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

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

United Kingdom

England

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

Sponsor information

Organisation
King's College London Enterprises (UK)

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Industry

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