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Safety and tolerability of BR38 in healthy volunteers: a phase I study

Submission date 13/05/2008	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 15/05/2008	**Overall study status** Completed	
Last Edited 12/04/2012	**Condition category** Other	

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
BR38-001

Study information

Scientific Title

Study objectives
The primary objective is to determine safety and tolerability of ascending single intravenous bolus injection doses of BR38 in healthy male volunteers. The secondary objective is to evaluate the imaging efficacy of BR38 in the myocardium and in the liver.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval submitted to Brent Medical Ethics Committee on the 29th April 2008.

Study design
Randomised, single-blind, placebo-controlled, ascending dose, single-site study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

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
Healthy volunteers

Interventions
One first pilot volunteer will be included at a fixed dose. Thirty six volunteers will then be studied in six-dose groups of six subjects (dose range: 0.005 to 0.32 µl/kg). In each group, four volunteers will be randomly assigned to receive BR38 and two volunteers to receive placebo. Each volunteer will receive a unique intravenous administration. The total duration of volunteer participation in the study from the admission to discharge is anticipated to be five days. The procedure associated with administration will be completed within 20 minutes.

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)

BR38

Primary outcome measure
Safety parameters. All safety parameters will be assessed from the enrolment of the patient and continue for 72 hours post dose at different time points.

Secondary outcome measures
Imaging quality. The image quality will be assessed up to one hour following the intravenous injection.

Overall study start date
15/06/2008

Completion date
31/12/2008

Eligibility

Key inclusion criteria
1. Male volunteer
2. Aged at least 18 years up to 35 years
3. Has a body mass index (BMI) of approximately 18 - 29 kg/m^2 and maximum weight of 100 kg
4. Absence of patent foramen ovale is confirmed by echocardiography
5. Is in good health as determined by medical history, physical examination, neurological examination, electrocardiogram, haematology, plasma chemistry, urinalysis and serology
6. Provides written informed consent and is willing to comply with protocol requirements

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
35 Years

Sex
Male

Target number of participants
37 healthy volunteers in total

Key exclusion criteria
1. Has any known allergy to one or more of the ingredients of the investigational product
2. Has received an investigational compound within 30 days before admission into this study
3. Has any medical condition or other circumstances which would significantly decrease the chances obtaining reliable data, achieving study objectives, or completing the study and/or post-

dose follow-up examinations
4. Had a clinical significant illness within 30 days preceding admission to the study
5. With no visualisation of left ventricle at basal echocardiography and/or without a good B mode ultrasound window for liver at screening
6. Is determined by the investigator that the subject is clinically unsuitable for the study

Date of first enrolment
15/06/2008

Date of final enrolment
31/12/2008

Locations

Countries of recruitment
Italy

United Kingdom

Study participating centre
Via XXV Aprile 4
San Donato Milanese
Italy
20098

Sponsor information

Organisation
Bracco Imaging S.p.A (Italy)

Sponsor details
Via Folli 50
Milan
Italy
20134

Sponsor type
Industry

Website
http://www.bracco.com/

ROR
https://ror.org/03wjptj96

Funder(s)

Funder type
Industry

Funder Name
Bracco Imaging S.p.A (Italy)

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	01/08/2011		Yes	No