

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

Submission date 13/05/2008	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 15/05/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 12/04/2012	Condition category Other	<input type="checkbox"/> 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

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/m² 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