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Evaluation of the diagnostic quality of manganese chloride tetrahydrate (CMC-001©) in liver magnetic resonance imaging in patients with liver metastases in comparison to gadolinium benzyloxypropionictetraacetate (BOPTA): a randomised cross-over phase III trial

Submission date 25/04/2007	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 01/06/2007	**Overall study status** Completed	
Last Edited 21/09/2007	**Condition category** Cancer	

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
CMC-P 004

Study information

Scientific Title

Study objectives
The primary objective is to assess the feasibility of manganese chloride tetrahydrate (CMC-001©) as a contrast medium in liver Magnetic Resonance Imaging (MRI) scanning in patients with liver metastases in comparison with gadolinium Benzyloxypropionictetraacetate (BOPTA) (MultiHance©) MRI.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received from the Regional Ethics Board in Stockholm on the 30th March 2005 (ref: 2005/305-31/1).

Study design
The study will be of a single centre, randomised and open cross-over design.

Primary study design
Interventional

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Colorectal cancer

Interventions
Each patient will have two MRI sessions, one with each product. This means that each patient will be his/her own control. The evaluation of MR images will be performed by two independent observers. The final evaluation will however be made in consensus.

When a suitable patient arrives at the clinic he/she will be informed about the trial both orally and in writing and is offered a to take part in the trial with two different MRI sessions, one with Gadolinium BOPTA and a second MRI with CMC-001© as contrast. After that he/she will sign the informed consent form.

The patients will visit the clinic three times:
1. For screening and eligibility test
2. For MR imaging of the first contrast
3. For MR imaging of the second contrast

After this, they will be called by phone 24 and 48 hours and asked about Adverse Events (AEs).

The order of administration of the two contrast agents is randomised. MRI after CMC-001© is performed three hours after contrast and MRI after MultiHance©, the comparator, is performed two hours after contrast.

Electrocardiogram (ECG), vital signs, blood for laboratory analyses and urine is drawn at screening and after MRI.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Manganese chloride tetrahydrate (CMC-001©) and gadolinium BOPTA (MultiHance©).

Primary outcome(s)
The primary objective is to assess the feasibility of CMC-001© as a contrast medium in liver MRI scanning in patients with liver metastases in comparison with gadolinium BOPTA (MultiHance©) MRI.

Key secondary outcome(s))
The secondary objectives are to further evaluate the safety and tolerability of CMC-001© in patients:
1. ECG, vital signs, blood for laboratory analyses and urine is drawn at screening and after MRI
2. AEs are asked for during the whole trial as well as at the phone calls 24 and 48 hours after contrast

Completion date
30/06/2007

Eligibility

Key inclusion criteria
1. Signed written informed consent after oral and written information about the study has been given by the investigator
2. Patients with one to six liver metastases from colorectal cancer verified with other methods
3. Men or women over 18 years old
4. The patient is conscious and co-operative

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex

All

Key exclusion criteria
1. Clinically relevant medical history or abnormal physical findings which could interfere with the safety or objectives of the study as judged by the investigator
2. Clinically relevant Electrocardiogram (ECG), haematology, clinical chemistry, serology and urine chemistry abnormalities. This is based on the judgement of the treatment physicians
3. Allergy to any of the study product compounds
4. Drug or alcohol abuse by asking the patient at screening
5. Patients who are deemed to be unsuitable for any other reason in the opinion of the investigator
6. Participation in another clinical study concerning another contrast preparation within the last three months or seven days after this study
7. Previous inclusion in this study
8. Pregnancy after randomisation at the day of MRI before contrast
9. The patient is scheduled to receive intravascular iodinated contrast medium within 24 hours after this study
10. The patient is being investigated on an emergency basis
11. The patient has newly discovered unstable diabetes or undergoes haemodialysis or peritoneal dialysis
12. The patient has a known or suspected clinically severe concurrent illness that may influence the renal function or has undergone kidney, liver or bone marrow transplantation
13. The patient has a concurrent severe illness in the Gastrointestinal (GI) tract like paralysis or malabsorption or clinically manifest icterus
14. Known Human Immunodeficiency Virus (HIV) infection or Acquired Immune Deficiency Syndrome (AIDS)
15. Known hepatitis
16. Known cirrhosis
17. The patient has uncompensated cardiac failure (cardiac failure New York Heart Association [NYHA] grade IV)
18. A patient may be excluded during the trial based on the clinical judgement of the clinician or the radiologist

Date of first enrolment
01/04/2005

Date of final enrolment
30/06/2007

Locations

Countries of recruitment
Sweden

Study participating centre
Lars Vedin AB
Stockholm
Sweden
SE-114 75

Sponsor information

Organisation
Copenhagen Malmö Contrast AB (CMC Contrast AB) (Sweden)

ROR
https://ror.org/015x46y72

Funder(s)

Funder type
Industry

Funder Name
Copenhagen Malmö Contrast AB (CMC Contrast AB) (Sweden)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration