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Evaluation of the diagnostic efficacy of manganese chloride tetrahydrate in liver magnetic resonance imaging in patients with liver metastases: a randomised, parallel group, open-label phase II trial

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Registration date 01/06/2007	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 19/10/2021	**Condition category** Cancer	[ ] Individual participant data [ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Lars Vedin

Contact details
Floragatan 13
Stockholm
Sweden
SE-114 75
+46 (0)8 5064 5751
lv@cmc-contrast.se

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CMC-P003

Study information

Scientific Title
Evaluation of the diagnostic efficacy of manganese chloride tetrahydrate in liver magnetic resonance imaging in patients with liver metastases: a randomised, parallel group, open-label phase II trial

Study objectives
Primary objectives:
The primary objective is to assess the efficacy and the time-response of manganese chloride tetrahydrate (CMC-001©) in two doses as a contrast medium in liver Magnetic Resonance Imaging (MRI) scanning.

Secondary objectives:
The secondary objective is to further evaluate the safety and tolerability of CMC-001© in patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received from the local ethics committee (Ethik-Kommission des Landes Berlin) on the 8th March 2006 (ref: EK 5 302/05).

Study design
This is an open, parallel group, randomised, single dose, single centre study in patients diagnosed with liver metastases.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet

Health condition(s) or problem(s) studied
Liver magnetic resonance imaging in patients with liver metastases

Interventions
The trial was open meaning that all patients had active drug. There was no comparator.

Each patient will visit the clinic on three occasions:
1. The screening visit
2. For dosing and MR imaging
3. For a follow-up

In addition, a telephone follow-up is performed 48 hours after administration of CMC-001©. The total study duration for each patient is not more than 10 days. The patients are assessed by MR imaging pre-dose and 1, 2, 3, and 6 hours post dose.

Two different doses were used: Full dose and Half dose. Every patient was randomised to one of these doses. After 24 hours the patients returned to the clinic for a safety follow up and all patients were contacted by telephone after 48 hours when Adverse Events (AEs) were asked for.

Patients also provided blood samples for safety blood tests and blood sampling for manganese analysis.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Manganese chloride tetrahydrate (CMC-001©)

Primary outcome measure
The primary objective is to assess the efficacy and the time-response of CMC-001© in two doses as a contrast medium in liver MRI scanning.

CMC-100 is a contrast agent taken by the oral route intended for use in MRI scanning of the liver, gallbladder and surrounding tissues. In this phase II trial the intention was to find out how well liver metastases could be visualised in contrast to the surrounding healthy liver tissue one, two, three, four and six hours after contrast in order to find the time response of CMC-001.

To this end a MRI image taken before contrast was compared to a MRI picture taken at the different time points after contrast by two independent observers. 48 hours after contrast the patients were called on the phone out of safety reasons in order to find out if they had experienced any adverse events.

Secondary outcome measures
The secondary objective is to further evaluate the safety and tolerability of CMC-001© in patients:
1. Vital signs is monitored at screening, before contrast and 1, 2, 3, 4, 6 and 24 hours after contrast
2. Electrocardiogram (ECG) is measured at screening, 6 and 24 hours after contrast
3. Clinical laboratory- and urine analyses are analysed at screening and 24 hours after contrast
4. Blood samples for manganese analysis are drawn before contrast and 3 and 24 hours after contrast
5. AEs are asked for during the whole trial including at 24 and 48 hours

Overall study start date

01/08/2005

Completion date
31/12/2007

Eligibility

Key inclusion criteria
1. Men or women over 18 years old
2. Patients with not more than 10 liver metastases verified with a biphasic multiscan (greater than or equal to 16) spiral slice Computed Tomography (CT) less than two weeks prior to the screening visit. At least two days should elapse between the CT-scan and the study start to allow the CT-scan contrast product to disappear
3. Signed written informed consent after oral and written information about the study has been given by the investigator
4. The patient is conscious and co-operative

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
20

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 haematology, clinical chemistry, serology and urine chemistry abnormalities. This is based on the judgement of the treating physicians
3. Concomitant diseases which can interfere with gastrointestinal absorption e.g. malabsorption, gastrectomi or other major surgical interventions in the Gastrointestinal (GI) tract
4. Allergy to any of the study product compounds
5. Drug or alcohol abuse by asking the patient at screening
6. Participation in another clinical study concerning another contrast preparation within the last four weeks or scheduled seven days subsequent to this study
7. Previous inclusion in this study
8. Pregnancy (checked at visit two by dip-stick)
9. The patient is scheduled to receive contrast medium intravascular within three days after this study
10. Any other contrast product within two days before the study start
11. The patient is being investigated on an emergency basis
12. The patient has newly discovered unstable diabetes or undergoes haemodialysis or

peritoneal dialysis
13. The patient has a concurrent illness that may influence the renal function or has undergone kidney transplantation
14. The patient has a clinically relevant concurrent illness in the GI tract or clinically manifest icterus
15. Known Human Immunodeficiency Virus (HIV) infection or Acquired Immune Deficiency Syndrome (AIDS)
16. Hepatitis
17. Liver cirrhosis
18. The patient has uncompensated cardiac failure (cardiac failure New York Heart Association [NYHA] grade IV)
19. Patients who are deemed to be unsuitable for any other reason in the opinion of the investigator

Date of first enrolment
01/08/2005

Date of final enrolment
31/12/2007

Locations

Countries of recruitment
Germany

Sweden

Study participating centre
Floragatan 13
Stockholm
Sweden
SE-114 75

Sponsor information

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

Sponsor details
c/o Lars Vedin AB
Floragatan 13
Stockholm
Sweden
SE-114 75
+46 (0)8 5064 5751
lv@cmc-contrast.se

Sponsor type
Industry

Website
http://www.cmc-contrast.se

ROR
https://ror.org/015x46y72

Funder(s)

Funder type
Industry

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

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