

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

Submission date 24/04/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 01/06/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 19/10/2021	Condition category Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

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-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

Study type(s)

Diagnostic

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(s)

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.

Key secondary outcome(s)

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

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

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 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, gastrectomy 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)

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