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Evaluation of the diagnostic efficacy of manganese chloride tetrahydrate (CMC-001©) in magnetic resonance cholangiography in patients with suspected liver lesions: a randomised, parallel group, open-label phase II trial

Submission date 30/04/2007	**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 19/10/2021	**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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CMC-P005

Study information

Scientific Title
Evaluation of the diagnostic efficacy of manganese chloride tetrahydrate (CMC-001©) in magnetic resonance cholangiography in patients with suspected liver lesions: a randomised, parallel group, open-label phase II trial

Study objectives
The primary objective is to assess the efficacy and the time-response of manganese chloride tetrahydrate (CMC-001©) in two dose levels as a contrast medium in Magnetic Resonance (MR)-cholangiography and 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 regional ethical committee in Gothenburg on the 7th September 2006 (ref: 235-06).

Study design
This study is an open label, parallel group, randomised, single centre study in patients with suspected liver lesions.

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
Magnetic resonance imaging of the liver, bile ducts and the gall bladder.

Interventions

Patients with suspected liver lesions will be given either a full dose (1.6 g) or half dose (0.8 g) of CMC-001©. A total of 16 fully evaluable patients will be included, 8 patients in each treatment arm. The study will be conducted at one site in Sweden.

Each patient will visit the clinic on three occasions:
1. The screening visit
2. For Magnetic Resonance Imaging (MRI)
3. For a follow-up

In addition, a telephone follow-up will be 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 MRI at pre-dose and 2.5 and 4 hours post dose.

Every patient will have three visits to the clinic at screening when MRI is done and blood samples for laboratory analyses is done, at the treatment day when two MRIs are done at 2.5 hours and 4 hours after contrast. The third occasion is a visit to the clinic 24 hours after contrast for safety reasons with new blood samples for laboratory testing is drawn. All patients will also be contacted by telephone 48 hrs after contrast when Adverse Events (AEs) will be asked for.

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 dose levels as a contrast medium in MR-cholangiography and to further evaluate the safety and tolerability of CMC-001© in patients.

Secondary outcome measures
1. To assess if CMC-001©-enhanced MR-cholangiography provides an equally good or improved image quality of the non-dilated biliary tree in comparison to T2-weighted MR cholangiography
2. To assess and compare the visualisation and delineation of focal liver lesions before contrast and after 2.5 and 4 hours after administration of CMC-001©
3. To assess the extent to which the pancreatic duct is filled 2.5 and 4 hours post administration of CMC-001©

Overall study start date
01/05/2006

Completion date
31/12/2007

Eligibility

Key inclusion criteria

1. Men or women over 18 years old
2. Patients that are referred for MR imaging of the liver for suspected liver pathologies indicated by ultra-sound or Computed Tomgraphy (CT) meriting further investigation
3. Signed written informed consent
4. The patients are conscious and co-operative

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
16

Key exclusion criteria
1. 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, based on the judgement of the investigator
3. Concomitant diseases which can interfere with gastrointestinal absorption, e.g., malabsorption, gastrectomy, Irritable Bowel Disease (IBD) or major surgical interventions in the Gastrointestinal (GI) tract
4. Patients who has undergone papillotomy
5. Patients who have MR contraindications according to the hospital checklist, e.g., pacemaker
6. One or more tumour greater than 10 cm, or several tumours greater than 5 cm, as judged by ultra-sound or CT
7. Allergy to any of the study product ingredients
8. Drug or alcohol abuse
9. Participation in another clinical study concerning pharmaceuticals
10. Previous inclusion in this study
11. Pregnancy (checked at visit two by pregnancy test when relevant)
12. Patients scheduled to receive contrast medium intravascularly within two days before inclusion or within three days after the CMC-001© administration
13. Patients with newly discovered unstable diabetes or undergoing haemodialysis or peritoneal dialysis
14. Known Human Immunodeficiency Virus (HIV) infection or Acquired Immune Deficiency Syndrome (AIDS)
15. Confirmed or suspected acute hepatitis
16. Bilirubin less than 40 µmol/l
17. Sepsis
18. The patient has a non-compensated cardiac failure (cardiac failure New York Heart

Association [NYHA] grade four)
19. Patients who are deemed to be unsuitable for any other reason in the opinion of the investigator

Date of first enrolment
01/05/2006

Date of final enrolment
31/12/2007

Locations

Countries of recruitment
Sweden

Study participating centre
Lars Vedin AB
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Sponsor information

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

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Sponsor type
Industry

Website
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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