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Evaluation of the diagnostic quality of manganese chloride tetrahydrate (CMC-100©) in liver magnetic resonance imaging in patients with known liver metastases: a phase II trial

Submission date
23/04/2007

Registration date
01/06/2007

Last Edited
19/10/2021

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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-P002

Study information

Scientific Title

Evaluation of the diagnostic quality of manganese chloride tetrahydrate (CMC-100©) in liver magnetic resonance imaging in patients with known liver metastases: a phase II trial

Study objectives
To assess the fasibility of manganese chloride tetrahydrate (CMC-001©) as a contrast medium in liver Magnetic Resonance Imaging (MRI) scanning.

The secondary objectives are 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 official board of the UMC St Radboud of Nijmegen on the 25th May 2004 (ref: SE/AMO 0339).

Primary study design
Interventional

Study design
The study was open and non-randomised, with each patient being his own control. The evaluation of the MR images was performed by two independent observers.

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Verified liver metastases

Interventions
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, the first phase II trial, the intention was to find out how well liver metastases could be visualised in contrast to the surrounding healthy liver tissue. To this end a MRI image taken before contrast was compared to a MRI picture taken three hours after contrast by two independent observers. Some of the patients also had a third MRI 24 hours after contrast in order to see if the gallbladder could be visualised. 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 (AEs).

No interventions besides the MRI and a screen of blood samples for safety analyses and a special blood sample for manganese alalyse were done.

Intervention Type
Drug

Phase
Phase II

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

Primary outcome(s)
The primary endpoint was efficacy. The MR image before contrast was compared to the MR image three hours after contrast and in a small number of patients also a MR image 24 hours after contrast.

Key secondary outcome(s)
Secondary parameters was the safety of the contrast. AEs were recorded as long as the patients were staying at the clinic and were called 48 hours after contrast and interviewed about any untoward experiences.

Completion date
01/03/2006

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 liver metastases verified with other imaging techniques
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 haematology, clinical chemistry, serology and urine chemistry abnormalities. This is based on the judgement of the treatment physicians
3. Use of any prescribed, over-the-counter or herbal medication one week prior to entering the study, which might interfere with the safety or the objectives of this study
4. Use of all types of products containing manganese, vitamin D or products containing amino acids during the examination day until after the 24-hour examination
5. Allergy to any of the study product compounds
6. Drug or alcohol abuse by asking the patient at screening
7. Patients who are deemed to be unsuitable for any other reason in the opinion of the

investigator
8. Participation in another clinical study concerning another contrast preparation within the last three months or seven days after this study
9. Previous inclusion in this study
10. Pregnancy
11. The patient is scheduled to receive iodinated contrast medium intravascular within three days after this study
12. The patient is being investigated on an emergency basis
13. The patient has newly discovered unstable diabetes or undergoes haemodialysis or peritoneal dialysis
14. The patient has a concurrent illness that may influence the renal function or has undergone kidney transplantation
15. The patient has a concurrent illness in the Gastrointestinal (GI) tract or clinically manifest icterus
16. Known Human Immunodeficiency Virus (HIV) infection or Acquired Immune Deficiency Syndrome (AIDS)
17. Hepatitis
18. The patient has uncompensated cardiac failure (cardiac failure New York Heart Association [NYHA] grade four)
19. A patient may be excluded during the trial based on the clinical judgement of the clinician or the radiologist

Date of first enrolment
01/05/2004

Date of final enrolment
01/03/2006

Locations

Countries of recruitment
Netherlands

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