

Determination of volume and surface area of intramuscular oil depots during body clearance using MRI

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The aim of this research is to determine the surface area of an oil depot during oil clearance. This is relevant for the release rate and therefore for the absorbed amount of active substance in blood. The volume is important for the interstitial...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Administration site reactions
Study type	Interventional

Summary

ID

NL-OMON41775

Source

ToetsingOnline

Brief title

Determination of intramuscular oil depots using MRI

Condition

- Administration site reactions

Synonym

decrease of surface area; clearance of oil

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: depot, mri, muscular, oil

Outcome measures

Primary outcome

The main study parameters are the determination of the surface (mm²) and the volume of the depot (mm³). During the study, the surface area and volume will decline, which is relevant to the release of the active substances in registered oil depots.

Secondary outcome

not applicable

Study description

Background summary

Controlled and sustained drug release and drug compliance are the major benefits of parenteral oil depot formulations. However, nowadays it is not possible to predict blood plasma concentrations, because there is no data for modeling available about release kinetics out of oil depots.

Formulation is still a matter of trial and error requiring a lot of extra in vivo studies. Therefore, to reduce this burden of experiments, there is a need for a scientific basis which would enable the formulation to design rather than to empirically find the suitable formulation.

Study objective

The aim of this research is to determine the surface area of an oil depot during oil clearance. This is relevant for the release rate and therefore for the absorbed amount of active substance in blood. The volume is important for the interstitial pressure in the muscle which plays a role in the uptake via the lymph. Furthermore, with this knowledge we can predict the release rate for all substances in oil depots by modeling.

Second, rate of oil clearance can be determined. This is relevant for multiple injections at the same injection place in multi dose therapy.

Study design

Proof of Principle / Observational study with invasive intervention

Intervention

Two placebo injections will be injected: one in the deltoid muscle and one in the vastus lateralis muscle of the volunteer. This is a sterile injection preparation. The injection volume is 1.0 mL.

Study burden and risks

The risks for volunteers to participate in our study are negligible. Extent of burden: one injection of an oil depot and eight MRI-scans. Because all volunteers are co-workers of the UMC Utrecht, no extra site visits are necessary.

The oil depot is an existing formulation with no active substances, so the injection is safe. MRI-scans are also safe and the scans are approved by Division Medical Imaging (UMC Utrecht).

There are no physical examinations, questionnaires or other tests that involve risks and burdens.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- male;
- age between 18 and 65 years;
- the patient is willing to give informed consent for participating in the study

Exclusion criteria

- female;
- depots in the upper arm is present at the time of inclusion;
- allergies to sesame oil and / or benzyl alcohol;
- medication that contribute to the clearance of oil;
- smoking
- claustrophobic
- pacemaker

Study design

Design

Study type: Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Other

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated):	22-01-2015
Enrollment:	8
Type:	Actual

Ethics review

Approved WMO	
Date:	17-12-2014
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO	
Date:	06-11-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL50387.041.14