Paracetamol as a tracer for plasma volume measurements: a proof of principle study.

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To determine if paracetamol can be used effectively and accurately in determining plasma volume as compared to the gold standard of 125I labeled ablumin in a non-pregnant patient population scheduled for plasmavolume measurement by I-125.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Pregnancy, labour, delivery and postpartum conditions
Study type	Interventional

Summary

ID

NL-OMON52675

Source
ToetsingOnline

Brief title
Paracetamol as a tracer

Condition

- Pregnancy, labour, delivery and postpartum conditions

Synonym
blood volume of the patient, plasma volume

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: paracetamol, plasma volume measurement, tracer

Outcome measures

Primary outcome

Comparison of the calculated plasma volumes using paracetamol and 125I labeled

albumin.

Secondary outcome

not applicable

Study description

Background summary

Plasma volume measurements are useful in determining which patients with (pre-)eclampsia in their history are at risk of developing (pre-)eclampsia in a future pregnancy. Lower plasma volumes combined with a high capillary leak, indicates a higher risk for repetition of (pre-)eclampsia in a next pregnancy. Currently I-125 is used in dertermination of plasma volume in non-pregnant patients. Due to the radioactivity its use is not possible in pregnant patients, which leaves us with no possibility to adeqately determine plasma volume during pregnancy. Paracetamol may be attractive as an alternative to measure plasma volume in pregnancy as it has a relatively long half life (2 hours in adults) compared to Evans blue and indocyanine green and is not harmful to the fetus as is 125I labeled albumin.

Study objective

To determine if paracetamol can be used effectively and accurately in determining plasma volume as compared to the gold standard of 125I labeled ablumin in a non-pregnant patient population scheduled for plasmavolume measurement by I-125.

Study design

The investigation is designed as a single center prospective, observational cohort study.

Intervention

Administration of 1000 mg paracetamol intravenously over 10 minutes. For every time blood samples are taken (4 times) an extra 3 ml will be withdrawn for the study.

Study burden and risks

The burden for patientents will be that they will get 1000 mg of paracetamol administered intravenously. This will take 10 minutes. During the study four times an extra blood sample will be taken. as the needed intravenous cannulae wil be present for the 125I labeled albumin study this will be no extra burden to the patients. There are no known risks to administering 1000 mg of paracetamol to non-allergic patients. Thera are no risks associated to withdrawing 12 ml of blood from a patient. There will be no direct benefit for patints. However this study may make it possible to safely determine plasma volume in pregant patients in the future. this in turn may lead to changes in clinical practice.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Over 18 years of age
(pre-)eclampsia in previous pregnancy
scheduled for plasma volume measurement
agree to participate in the study

Exclusion criteria

under the age of 18
pregnant
allergy for paracetamol
liver failure
refusal to participate in the study

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-11-2022
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	05-06-2020
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	27-12-2022
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 23031
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL70761.068.19
OMON	NL-OMON23031