Hem-col® as an alternative for standard laboratory testing in the follow up of patients after bariatric surgery

Published: 17-03-2018
Last updated: 12-04-2024

The main objective of this study is to compare Hem-Col® as a method to draw blood and measure the parameters used in the routine follow-up laboratory checks after bariatric surgery to the present standard method at the laboratory at the MC...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON46649

Source
ToetsingOnline

Brief title
The Hem-Col Study

Condition

- Other condition

Synonym
overweight

Health condition

obesitas

Research involving
Human

Sponsors and support

Primary sponsor: Slotervaartziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W,Labonovum BV.

Intervention

Keyword: Hem-Col, Venepuncture

Outcome measures

Primary outcome

The main study parameter will be the difference in levels of different blood parameters between the two tested methods. The levels of the following blood parameters will be studied: Hemoglobin, C-reactive protein, creatinine, calcium, cholesterol, triglycerides, glucose, Hemoglobin A1c, thyroid stimulating hormone, vitamin B1, vitamin B6, folic acid, vitamin B12, vitamin D, ferritin, parathyroid hormone.

Secondary outcome

NVT.

Study description

Background summary

In MC Slotervaart, one of the main medical centres for bariatric surgery, routine blood checks are performed to evaluate vitamin status and several other parameters in the follow up of bariatric patients. For this, patients have to visit a laboratory to have their blood drawn through venipuncture. Approximately nine different tubes of blood is drawn, requiring around 40 millilitres of blood. For analysing the blood, only a few millilitres is used. The remaining blood is wasted.
Hem-Col® is a new blood drawing system produced by Labonovum B.V. that makes it possible for patients to draw blood themselves at home using a finger stick. Capillary blood is collected in a tube containing a special fluid which allows storage of the blood sample for a few days before analysing. Patients can send

this blood sample to the laboratory for the assessments and do not have to visit the lab themselves anymore.

Study objective

The main objective of this study is to compare Hem-Col® as a method to draw blood and measure the parameters used in the routine follow-up laboratory checks after bariatric surgery to the present standard method at the laboratory at the MC Slotervaart.
The second objective of this study is to measure how patient friendly Hem-Col® is and if the product is indeed easy to use for our population.

Study design

We will conduct a method comparison study for validation of the Hem-Col® system. Standard follow up moments, including blood checks, after bariatric surgery are at 6 and 12 months and after that it is repeated annually. Patients included in this study will have their blood drawn at one of these moments through both methods at the same time. Both methods will be conducted by the researcher. After this, collected blood will be analysed and the result of both methods will be compared. At this time, patients will also get instructions for using the Hem-Col® system themselves at home. Also, an instruction manual will be handed out. Two weeks later, patients will be asked to draw blood themselves through this new method. They will be asked to fill in a questionnaire at this moment to evaluate how patient friendly the system is.

Study burden and risks

The procedure required for this study is almost similar to the current procedure. Patients will have their blood drawn through venepuncture just like they are used to do. The procedure will be extended with a few minutes because a second method for blood drawing, through the finger stick. No great burden or risks are associated with the Hem-Col® method. Using a finger stick can be painful in some cases, but this is only for a short time and can be neglected. After two weeks patients will draw blood through the Hem-Col® system again and will send this to the laboratory. They will be asked to fill in a questionnaire, which will require just a few minutes of their time.

Contacts

Public
Slotervaartziekenhuis

Louwesweg 6

Amsterdam 1066 EC
NL
Scientific
Slotervaartziekenhuis

Louwesweg 6
Amsterdam 1066 EC
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

-Patients who have undergone a laparoscopic roux and y gastric bypass, laparoscopic omega loop gastric bypass, laparoscopic redo gastric bypass, laparoscopic gastric sleeve, laparoscopic distal gastric bypass or laparoscopic duodenal switch.
-Patients having a routine blood check after 6 months or for the routine annual check.
-Informed consent to participate.

Exclusion criteria

None.

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	100
Type:	Anticipated

Ethics review

Approved WMO

Date:	17-03-2018
Application type:	First submission
Review commission:	METC Slotervaartziekenhuis en Reade (Amsterdam)

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	NL63727.048.17