The effect of a Fasting mimickINg Diet on the immune system: an exploratory study

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To contribute to the evaluation of 'fasting mimicking diet' application in oncotherapeutic setting and to gain insight on the underlying mechanisms in response to a fasting mimicking diet. This explorative study focuses on the immune...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON51212

Source
ToetsingOnline

Brief title
FIND

Condition

- Other condition

Synonym
n.a.

Health condition

gezonde proefpersonen

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Pink ribbon (financiering voor DIRECT studie P135.35)

Intervention

Keyword: Diet, Fasting, Immunomodulation, RNA-nanostring

Outcome measures

Primary outcome

The changes in gene expression profile and pathway signaling in white blood

cells using RNA nanostring analysis on whole blood samples. The blood samples

are collected at 3 different time points in a fed state, fasted state and after

the second cycle of the fasting mimicking diet.

Secondary outcome

- Flow cytometry on peripheral blood mononuclear cells, including confirmation

of gene expression profile alterations on the protein level.

- Change in plasma concentration of IGF1, glucose and ketone bodies.

- Evaluation of experienced side effects from FMD recorded in the toxicity

forms in the Case report form (CRF) assessed on day 1 and 31.

Study description

Background summary

A preclinical stuy by Di Biase et al (2016), showed that short-term fasting protects tumor-bearing mice against the toxic effects of chemotherapy, improves the CD8+ T cell intratumour infiltration, while enhancing the chemotherapy efficacy. This preclinical research suggests that fasting potentially has a beneficial effect on effector T-cells of the immune system, which could aid antitumorimmunity. However the effect of fasting on the immune system in humans

is still largely unknown, especially in an oncotherapeutic setting.
The DIRECT-study (DIetary REstriction as an adjunct to neoadjuvant ChemoTherapy for HER2 negative breast cancer) examined the effects of six neoadjuvant chemotherapy cycles with or without peri-chemotherapeutic fasting mimicking diet and investigated the therapeutic efficacy and toxicity.
In this explorative study the effect of a fasting mimicking diet on the immune cells and -response will be investigated in healthy volunteers. This will provide direction for translational experiments in future clinical trials.

Study objective

To contribute to the evaluation of 'fasting mimicking diet' application in oncotherapeutic setting and to gain insight on the underlying mechanisms in response to a fasting mimicking diet. This explorative study focuses on the immune system and -response after two cycli of a four day fasting mimicking diet. Performing this explorative study will provide direction regarding what change in which type of immune cells can be observed. These findings will aid in the setup and interpretation of future translational experiments in the context of clinical studies building on the DIRECT study.

Study design

Observational research

Study burden and risks

Participation requires the healthy volunteers to adhere to 2 cycles of 4-day FMD provided by the LUMC. Participants could experience transient mild symptoms like headache, dizziness, fatigue and feeling hungry during FMD, due to consuming less calories. Another possible minimal risk is pain and hematoma during and/or after blood collection. The blood samples of 7 tubes (43,5ml total) will be taken at three time points. In addition the participants will fill out a toxicity questionnaire concerning any experienced side effects on day 31. The appointments require three visits, each less than 30 minutes.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- *18 years old
- BMI *18,5 and *25kg/m2

Exclusion criteria

- Chronic disease or active infection
- Medication use other than contraceptive, during the last 12 weeks prior to inclusion.
- A history of allergy
- Blood or plasma donation in the last 12 weeks prior to inclusion.
- Participation in other medical research in the last 12 weeks prior to inclusion.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-11-2021
Enrollment:	8
Type:	Actual

Ethics review

Approved WMO

Date:	19-04-2021
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	16-08-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL76033.058.21

Study results

Date completed:	19-04-2022
Actual enrolment:	16