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Metabolic effects at two months from a fasting week

Submission date	**Recruitment status**	[X] Prospectively registered
12/03/2019	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
18/03/2019	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
16/08/2022	Other	

Plain English summary of protocol

Background and study aims
Fasting is an emerging practice as a preventive method. The media coverage of this nutritional method is increasing in Switzerland. The CIBE (Interlude Bien-être Center [www.interludebienetre.ch]) offers one week fast paid stays. The preventive properties of fasting are supported by preclinical data and scattered clinical trials. Preclinical research on fasting and caloric restriction suggests a beneficial effect on health. These benefits translate into increased longevity and decreased risk of heart disease and cancer. The aim of this study is to find out whether there is a persistence of metabolic effects after 2 months in non-diabetic people who are fasting for a week at CIBE.

Who can participate?
Clients at the Interlude Bien-être Center (Val d'Illiez, Valais, Switzerland) who voluntarily fast for a week

What does the study involve?
During the study, physical measurements (body composition, abdominal circumference, blood pressure, body temperature, body mass index, heart rate) and, for a selected group (more at risk of metabolic syndrome according to the measurements of abdominal circumference, body mass index, blood pressure), laboratory tests (lipid profile, blood glucose, protein C reactive, IGF-1) are carried out. These values are recorded at the beginning and end of the fast, and two months after the start of the fast. Forms on eating habits and physical activity are completed before fasting and two months later.

What are the possible benefits and risks of participating?
The participants thanks to these tests benefit from a screening (e. g. blood pressure, lipid profile, variation of body composition). Furthermore, they should return to the Center Interlude Bien-être two months after fasting. The greatest risk is related to blood sampling which causes an injury to the elbow crook, which can bleed, cause an ecchymosis (discoloration), a hematoma (swelling) and, rarely, become complicated by infection and thrombosis.

Where is the study run from?
Centre Interlude Bien-Être (Switzerland)

When is the study starting and how long is it expected to run for?
April 2018 to June 2021

Who is funding the study?
The study is partially funded by the company Interlude Bien-être Sarl. Research and statistical analysis costs are borne by researchers (Mauro Frigeri, MD; Valeria Galetti, PhD; Marica Brnic Bontognali, PhD)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
BASEC2019-00415

Study information

Scientific Title
Observational study on metabolic effects for clients who fast for one week at the Centre Interlude Bien-être, two months after the onset of fasting: body composition and plasma LDL cholesterol concentration

Study objectives
The voluntary realisation of a week-long fast has objective metabolic effects that persist at two months from the beginning of the fast.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 24/04/2019, Commission cantonale d'éthique de la recherche sur l'être humain du canton de Vaud (avenue de Chailly 23, 1012 Lausanne, Switzerland; +41 21 316 18 30; secretariat.cer@vd.ch), ref: 2019-00415

Study design
Observational cohort study lasting 2 years

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Clients of the Centre Interlude Bien-être, where a week of fasting is done voluntarily

Interventions
Study participants are recruited from clients at the Interlude Bien-être Center (Val d'Illiez, Valais, Switzerland) who voluntarily fast for a week. Body composition, blood pressure (TA), body mass index (BMI), abdominal circumference (CA), temperature, heart rate and, in a group selected (BMI ≥ 30kg/m2, or TA ≥ 130/85mmHg or antihypertensive drug, or CA ≥ 80cm in women and ≥ 94cm in men) for blood sampling, blood glucose, lipid profile, insulin-like growth factor 1 (IGF-1), C-reactive protein (CRP) are compared between before fasting, after fasting and at two months from the beginning of fasting. Forms describing diet and physical activity are completed before fasting and two months after the start of fasting.

Intervention Type
Behavioural

Primary outcome measure
Plasma LDL cholesterol (laboratory analysis in mmol/l) measured at the onset of fasting and two months after the beginning of the fasting week, in the group selected for blood sampling

Secondary outcome measures
1. Total cholesterol (mmol/l), HDL cholesterol (mmol/l), triglycerides (mmol/l), blood glucose (mmol/l), CRP (mg/l) and IGF-1 (ng/ml), in the group selected for blood sampling (laboratory analysis), and variation in BMI (kg/m2), CA (cm), TA (mmHg), heart rate (/min), temperature (°C), measured at the beginning of the fast and 2 months after

2. The same measures (and LDL cholesterol) at the beginning and at the end of the fast
3. Fat-free mass measured by bioelectrical impedance analysis at 50 kHz with Nutrigard MS performed at the beginning, end and 2 months after the beginning of the fast

Overall study start date
30/04/2018

Completion date
30/06/2021

Eligibility

Key inclusion criteria
1. Informed consent
2. Participating in a fasting week at the Centre Interlude Bien-être
3. Age ≥ 20 years, ≤ 70 years

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
100 (20 included in the group selected for the blood test)

Total final enrolment
40

Key exclusion criteria
1. Diabetes mellitus or taking glucose-lowering medication
2. BMI <18kg/m2
3. Known eating disorders (orthorexia, anorexia, bulimia)
4. Known metabolic pathologies that contraindicate fasting (e.g. deficiencies gluconeogenesis)
5. Pregnant women or during the lactation period

Date of first enrolment
30/04/2019

Date of final enrolment
31/05/2021

Locations

Countries of recruitment
Switzerland

Study participating centre
Centre Interlude Bien-Être
Val-d'Illiez (Valais)
Switzerland
1873

Sponsor information

Organisation
Fondazione Hospice Ticino

Sponsor details
Groupe pour l'étude du jeûne (Mauro Frigeri, MD; Valeria Galetti, PhD; Marica Brnic Bontognali, PhD)
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Sponsor type
Other

Website
http://www.digiunoesalute.ch

Funder(s)

Funder type
Industry

Funder Name
Interlude Bien-être Sarl

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
01/01/2023

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		17/01/2021	11/05/2021	Yes	No
Protocol file	version 1.2	07/04/2019	16/08/2022	No	No