Whole-Body Cryotherapy (WBC) for COVID-19 recovered patients having anosmia or severe hyposmia

Protocol summary

Study aim
Demonstrating that repeated cold exposure would improve olfactory function. It was hypothesized that high-dose WBC (five 3-min long sessions of whole body cryotherapy over 1 week) would result in more benefits that low-dose WBC (two 3-min long sessions of whole body cryotherapy over 1 week).

Design
Pilot randomized controlled trial with a parallel group design of forty-five COVID-19 recovered patients with anosmia or severe hyposmia, enrolled between February 2021 and April 2021. Olfactory function was assessed before and after intervention for each participant.

Settings and conduct
WBC sessions were conducted at the Cryotherapy Center of Bezannes, France. The day before and the day following the assigned intervention, each participant was examined by a physician who evaluated their sense of smell.

Participants/Inclusion and exclusion criteria
Participants had to be COVID-19 recovered patients with residual anosmia or severe hyposmia after diagnosis of SARS-CoV-2 infection (positive PCR test). Participants with medical contraindications to Whole-Body Cryotherapy were excluded.

Intervention groups
There were two intervention groups and one control group. In the first intervention group (high-dose WBC) participants received daily sessions (5 days over one week) of WBC. Each session was 3 minutes in length and was performed in a cryotherapy chamber exposing individuals to freezing dry air at a temperature of -90°C. In the second intervention group (low-dose WBC), the intervention was similar but participants received only two WBC sessions over one week.

Main outcome variables
Our main outcome variable was participants' score change on a Visual Analog Scale. We used a straight horizontal line of 100 mm with "0" indicating no loss of the sense of smell compared to what it was before COVID-19 infection and "100" indicating complete loss.

General information

Reason for update
Acronym
CRYOTAN
IRCT registration information
IRCT registration number: IRCT20210708051817N1
Registration date: 2021-07-14, 1400/04/23
Registration timing: retrospective

Last update: 2021-07-14, 1400/04/23
Update count: 0

Registration date
2021-07-14, 1400/04/23

Registrant information
Name
Fabien LEGRAND
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-02-01, 1399/11/13
Expected recruitment end date
2021-05-01, 1400/02/11
Actual recruitment start date
2021-02-15, 1399/11/27
Actual recruitment end date
2021-04-19, 1400/01/30

Trial completion date
2021-05-01, 1400/02/11

Scientific title
Whole-Body Cryotherapy (WBC) for COVID-19 recovered patients having anosmia or severe hyposmia

Public title
Whole Body Cryotherapy (WBC) for treating anosmia / hyposmia

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
recovered COVID-19 patients (asymptomatic for at least 3 weeks) anosmia or severe hyposmia (more than 50 percent reduction of olfactory acuity)

Exclusion criteria:
medical contraindications to Whole-Body Cryotherapy

Age
From 18 years old to 79 years old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: 42
Actual sample size reached: 45

Randomization (investigator's opinion)
Randomized

Randomization description
A permutated block randomization design at the level of the individual was used, with a block size of three individuals. In each block of three, two patients were randomly assigned to the experimental groups (low-dose WBC, high-dose WBC) and one patient to the control group. This was done using sealed envelops. There was no allocation concealment.

Blinding (investigator's opinion)
Not blinded

Blinding description
Placebo
Not used

Assignment
Parallel

Other design features
empty

Secondary Ids
empty

Ethics committees

1
Ethics committee
Name of ethics committee
Ethics Committee of the Société Française de Cryothérapie Corps Entier

Street address
11 avenue du Tremblay

City
Paris

Postal code
75012 Paris

Approval date
2021-01-10, 1399/10/21

Ethics committee reference number
SFCCE-2021-3

Health conditions studied

1
Description of health condition studied
COVID-19 induced anosmia or severe hyposmia (defined as more than 50 percent of loss of sense of smell)

ICD-10 code
U07.1

ICD-10 code description
U07.1 COVID-19, virus identified

Primary outcomes

1
Description
participant's score change on the Visual Analog Scale measuring the loss of sense of smell

Timepoint
the day before and the day following intervention

Method of measurement
participant's self-report evaluation on a Visual Analog Scale 0-100 ; with "0" indicating complete loss of sense of smell compared to what it was before being infected by COVID-19; and "100" indicating full recovery of sense of smell.

Secondary outcomes
empty

Intervention groups

1
Description
Intervention group 1: high-dose Whole-Body Cryotherapy (WBC). Participants receive daily sessions of WBC in a cryotherapy chamber at temperature of -90°C. Sessions are 3 minutes in length. Intervention's duration is 5 days.

Category
Treatment - Other

2
Description
Intervention group 2: low-dose Whole-Body Cryotherapy (WBC). Participants receive daily sessions of WBC in a cryotherapy chamber at temperature of -90°C. Sessions are 3 minutes in length. Intervention's duration is 5 days.
are 3 minutes in length. Intervention's duration is 2 days.

**Category**
Treatment - Other

**Description**
Control group: participants in the control group received no WBC sessions

**Recruitment centers**

1. **Recruitment center**
   - Name of recruitment center: Cryotherapy Center "CRYOTERA"
   - Full name of responsible person: Bastien Bouchet
   - Street address: 7 rue Jules Méline
   - City: Bezannes
   - Postal code: 51430
   - Phone: +33 3 26 77 97 50
   - Email: bastien.bouchet@cryotera.fr

**Sponsors / Funding sources**

1. **Sponsor**
   - Name of organization / entity: The University of Reims Champagne Ardenne
   - Full name of responsible person: Fabien Legrand
   - Street address: 9 Boulevard de la Paix
   - City: Reims
   - Postal code: 51100
   - Phone: +33 3 26 91 38 90
   - Email: fabien.legrand@univ-reims.fr
   - Grant name: non pharmacological interventions
   - Grant code / Reference number: NPI-2021-2
   - Is the source of funding the same sponsor organization/entity?: Yes
   - Title of funding source: The University of Reims Champagne Ardenne
   - Proportion provided by this source: 100

**Person responsible for general inquiries**

Contact
- Name of organization / entity: The University of Reims Champagne Ardenne
- Full name of responsible person: Fabien Legrand
- Position: Assistant Professor
- Latest degree: Ph.D.
- Other areas of specialty/work: Health Promotion
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**Person responsible for scientific inquiries**

Contact
- Name of organization / entity: The University of Reims Champagne Ardenne
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- Position: Professor
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**Person responsible for updating data**

**Contact**
- **Name of organization / entity**: Société Française de Cryothérapie Corps Entier
- **Full name of responsible person**: Bastien Bouchet
- **Position**: Manager
- **Latest degree**: Master
- **Other areas of specialty/work**: Health Service Management

**Street address**
- 11 avenue du Tremblay

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**Province**
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**Postal code**
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**Phone**
- +33 1 41 74 43 56

**Email**
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**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**
- Yes - There is a plan to make this available

**Study Protocol**
- Yes - There is a plan to make this available

**Statistical Analysis Plan**
- Yes - There is a plan to make this available

**Informed Consent Form**
- Yes - There is a plan to make this available

**Clinical Study Report**
- Yes - There is a plan to make this available

**Analytic Code**
- Not applicable

**Data Dictionary**
- Not applicable

**Title and more details about the data/document**
- we will provide all collected deidentified participants’ data set in a .xls file

**When the data will become available and for how long**
- data set will be available as of 1 September 2021 for one full year

**To whom data/document is available**
- data set will be available for people working in academic institutions

**Under which criteria data/document could be used**
- data can be used for scientific purposes

**From where data/document is obtainable**
- person to be contacted: fabien.legrand@univ-reims.fr

**What processes are involved for a request to access data/document**
- write an email explaining what for you might need the data set

**Comments**