# Trial Description

## Title

**Prospective, randomised, placebo-controlled, double-blind, multicentre clinical investigation to evaluate the clinical performance and safety of LUVOS® HEALING EARTH imutox treatment in patients with recurrent Clostridioides difficile infection. (2020-08, LUVCDI)**

## Trial Acronym

**2020-08 (LUVCDI)**

## URL of the trial

**[---]***

## Brief Summary in Lay Language

**In this randomized, placebo-controlled study, the efficacy, tolerability and side effect profile in patients with acute C. difficile infection and associated gastrointestinal symptoms, such as diarrhea, of the natural product Luvos® Healing Earth, which has been in use and marketed for over 100 years, will be demonstrated. In this context, Luvos® Healing Earth is used in the follow-up of a successful antibiotic therapy to prevent a flare-up of the infection and/or the symptoms.**

## Brief Summary in Scientific Language

**The present clinical investigation will evaluate the toxin-binding effect of the well-characterized Healing Earth (Luvos® Healing Earth imutox), which is effective in the lumen of the intestine, in subjects with proven and antibiotically treated infection with Clostridioides difficile. Luvos® Healing Earth shows very good binding of toxin A (TcdA) in vitro, toxin B (TcdB) is less well bound in the presence of albumin. However, the albumin concentration in the faeces is low. In clinical practice, Healing Earth has shown to be effective in the treatment of milder cases of CDI. Subjects with confirmed CDI should be treated continuously with Luvos® Healing Earth p.o. for a period of 42 days after the current infection has been cured. Efficacy of Luvos® Healing Earth is expected based on the strong binding of bacterial toxins due to its ad- and absorption properties, thereby removing a substantial factor for flare-up and infection recurrence.**

## Do you plan to share individual participant data with other researchers?

**Yes**

## Description IPD sharing plan

**IPD Plan: Yes. Timeframe: Data requests can be submitted starting 3 months after publication of the article. Data will be made available for up to 24 months. Extensions will be considered on a case-by-case basis.**

**Criteria for Access: Access to study IPD data may be requested by qualified investigators conducting independent scientific research and will be granted after review and approval of a research proposal and statistical analysis plan (SAP) and completion of a data sharing agreement. The sponsor reserves the right to exclude certain variables or data sets from sharing. For more information or to submit an application, please contact info at luvos.de.**

## Organizational Data

- DRKS-ID: **DRKS00027358**
- Date of Registration in DRKS: **2022/02/22**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **no**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **2021-2392-evBO , Ethikkommission der Landesärztekammer Hessen**

## Secondary IDs

- Universal Trial Number (UTN): **U1111-1273-0575**

## Health condition or Problem studied

- ICD10: **A04.79 - [generalization A04.7: Enterocolitis due to Clostridium difficile]**
- ICD10: **A04 - Other bacterial intestinal infections**

## Interventions/Observational Groups

- Arm 1: **Luvos® Healing Earth imutox granules, (sachets) p.o. 3 x daily for 6 weeks. CE certified medical device CE0044**
- Arm 2: **Placebo granules, (sachets) p.o. 3 x daily for 6 weeks.**

## Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **patient/subject, investigator/therapist, caregiver, data analyst**
- Control: **Placebo**

Study Type: **Interventional**

Study Type Non-Interventional: **[---]***

Allocation: **Randomized controlled trial**

Blinding: **[---]***

Who is blinded: **patient/subject, investigator/therapist, caregiver, data analyst**

Control: **Placebo**

- Purpose: **Prevention**
- Assignment: **Parallel**
- Phase: **IV**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **No**

### Primary Outcome

**Occurrence of a first or second CDI relapse, with a new episode of diarrhea, positive stool test for toxigenic C. difficile following clinical cure of the first infection.**

### Secondary Outcome

**Global cure, defined as clinical cure of the first infection or relapse episode and no further CDI relapse through week 6; Global cure, defined as clinical cure of the recurrent (Second/further) infection or relapse episode and no further CDI relapse through week 6; Overall clinical cure after first or further infection; Reduction of the patient's clinical symptoms in case of a further relapse episode; Safety: Adverse events.**

## Countries of recruitment

- DE **Germany**
- RO **Romania**

## Locations of Recruitment

- Doctor's Practice **65396 Walluf**
- Medical Center **57074 Siegen**
- University Medical Center **97080 Würzburg**
- Medical Center **78464 Konstanz**
- Medical Center **13585 Berlin**
- University Medical Center **55131 Mainz**

## Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2022/03/01**
- Target Sample Size: **314**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **International**

### Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

### Additional Inclusion Criteria

**Females and Males aged ≥ 18 years with proven mild to moderate Clostridioides-difficile Infection (white blood cell count of < 15,000 cells/µl and a serum creatinine level < 1.5 mg/dl);**
**Patients with a first or multiple relapses of CDI diagnosed by the primary care or hospital physician, and treated with anti-infectives (max. of 14 days) according to current guidelines, and which fulfil the criteria of "Clinical Cure".**

### Exclusion criteria

**Patients who need to continue taking their other therapies (except antibiotics) for any underlying conditions during the treatment phase, but who require a change in dose or medication during the treatment phase and/or concomitant therapy that, at the discretion of the investigator, precludes inclusion; Patients with short bowel syndrome or intestinal stomas; Patients with severe or complicated course of CDI; Patients who have to take antibiotics regularly, i.e., definitely or with a high probability during the study, due to other diseases; Patients who need to continue antibiotic therapy (beyond visit 1) due to infectious disease of other organs, or who have undergone antibiotic therapy (except against CDI) within the 4 weeks prior to inclusion (visit 1) in this study; Known allergic reactions to Healing Earth or other loess preparations; Patients with Crohn's disease and ulcerative colitis; Chronic liver disease (Child-Pugh B and C); Chronic renal insufficiency; Pregnancy or desire to become pregnant; Others.**

## Addresses

■ **Primary Sponsor**

**Heilerde-Gesellschaft Luvos Just GmbH & Co. KG**
**Ms. Diplom-Volkswirtin Ariane Kaestner**
**Otto-Hahn-Straße 23**
**61381 Friedrichsdorf**
**Germany**

Telephone: **+49 6175/9323-0**
Fax: **+49 6175-9323-20**
E-mail: **Kaestner at luvos.de**
URL: **www.luvos.de**

■ **Contact for Scientific Queries**

**Privatpraxis**
**Ms. Dr. Julia Kleinhenz**
**Am Klingenweg 2a**
**65396 Walluf**
**Germany**

Telephone: **06123-71295**
Fax: **06123-7039968**
E-mail: **julia at drkleinhenz.de**
URL: **[---]***

■ **Contact for Public Queries**

**Heilerde-Gesellschaft Luvos Just GmbH & Co. KG**
**Otto-Hahn-Straße 32**
**61381 Friedrichsdorf**
**Germany**

Telephone: **+49 6175/9323-0**
Fax: **+49 6175-9323-20**
E-mail: **info at luvos.de**
URL: **www.luvos.de**

- **Collaborator, Other Address**

  **Heilerde-Gesellschaft Luvos Just GmbH & Co. KG**
  **Otto-Hahn-Straße 32**
  **61381 Friedrichsdorf**
  **Germany**

  Telephone: **+49 6175/9323-0**
  Fax: **+49 6175-9323-20**
  E-mail: **info at luvos.de**
  URL: **www.luvos.de**

## Sources of Monetary or Material Support

- **Commercial (pharmaceutical industry, medical engineering industry, etc.)**

  **Heilerde-Gesellschaft Luvos Just GmbH & Co. KG**
  **Ms. Diplom Volkswirtin Ariane Kaestner**
  **Otto-Hahn-Straße 32**
  **61381 Friedrichsdorf**
  **Germany**

  Telephone: **+49 6175/9323-0**
  Fax: **+49 6175-9323-20**
  E-mail: **info at luvos.de**
  URL: **www.luvos.de**

## Status

- Recruitment Status: **Recruiting planned**
- Reason, if "Recruitment stopped after recruiting started" or "Recruiting withdrawn before recruting started": **[---]***
- Reason, if Reason for Recruiting Stop "Other": **[---]***
- Study Closing (LPLV): **[---]***
- Number of Participants in Germany after Recruiting complete: **[---]***
- Total Number of Participants (all Sites worldwide) after Recruiting complete: **[---]***

## Trial Publications, Results and other documents

- trial protocol (mandatory for transfer to Studybox) **2020-08 CIP V 1.1**

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*