MICROB-PREDICT

MICROBiome-based biomarkers to PREDICT decompensation of liver cirrhosis and treatment response

D7.2 Registration number of clinical study in a WHO- or ICMJE-approved registry

Project acronym:	MICROB-PREDICT
Grant Agreement:	825694
Project Duration:	01 January 2019 – 31 March 2025 (75 months)
Version:	V1
Date:	24/09/2021
WP Leader:	Aleksander Krag (03 OUH)
Authors:	Aleksander Krag, Mads Israelsen, Nikolaj Torp (03 OUH), Jonel Trebicka (01 EFCLIF)
Due date of deliverable	Month 33
Actual submission date	28/09/2021
Dissemination level	PU

Abbreviations

CTIS	Clinical Trials Information System
EMA	European Medicine Agency
EFCLIF	European Foundation For The Study of Chronic Liver Failure
ICMJE	International Committee of Medical Journal Editors
OUH	Odense Universitetshospital
PRS	Protocol Registration and Results Systems
WHO	World Health Organization

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1. Executive Summary

The deliverable of the registration number of the clinical study (ALB-TRIAL) in a WHO- or ICMJE-approved registry is done in time. The work of the deliverable is based on the work from D7.1 (final version of study protocol), where the major study design items are now public in the ClinicalTrials.gov registry. The registration has undergone Protocol Registration and Results Systems (PRS) review of ClinicalTrials.gov and have been approved based on the submitted work. The ALB-TRIAL has been appointed ClinicalTrials.gov identifier: **NCT05056220**

2. Deliverable report

Clinical trial registries were browsed for those who fulfilled the WHO / ICMJE minimum of 24-item trial (Table 1) registration dataset to find a suitable registry for study registration. In the search, emphasize was put on registries that were: 1) accessible to the public at no charge, 2) open to all prospective registrants, 3) managed by a non-profit organization, 4) had mechanisms that ensured validity of data entry and finally 5) were electronically searchable. After the initial search, several options for registration appeared. The final decision on ClinicalTrials.gov was made based on the 1) wide acknowledgement of the clinical trial registry 2) acceptance from not only WHO / ICMJE but also many other key stakeholders (patient organizations, scientific organizations, regulatory- and ethical entities) of the MICROB-PREDICT consortium. Due to the European nature of MICROB-PREDICT and physical location of ALB-TRIAL study sites, the study will indeed be registered in a European Clinical Trial registry database as well. Depending on when this action will take place (prior to or after January 2022) either the EudraCT database or the newly developed Clinical Trials Information System (CTIS) of the European Medicine Agencies (EMA) will be the point of registration. This is planned to occur in tandem with the filling of the regulatory and ethical approval if the CTIS will be in place at the time of registration. The registration of the ALB-TRIAL in ClinicalTrials.gov can be viewed in appendix 1. The study details can furthermore be accessed with the ClinicalTrials.gov identifier: **NCT05056220**

As the study initiation is approaching, minor adjustments and additions are expected to be made to the clinical trial registration details. However, the history revision tool of ClinicalTrials.gov allow for comparisons between older and newer editions of the study details.

WHO 24-item list requirement	ClinicalTrials.gov equivalent
1. Primary Registry and Trial Identifying Number	ClinicalTrials.gov Identifier (NCT Number) - *assigned by system*
2. Date of Registration in Primary Registry	*Generated by system*
3. Secondary Identifying Numbers	Unique Protocol Identification Number, Secondary IDs
4. Source(s) of Monetary or Material Support	Name of the Sponsor, Collaborators
5. Primary Sponsor	Name of the Sponsor
6. Secondary Sponsor(s)	Collaborators
7. Contact for Public Queries	Facility Contact OR Central Contact Person
8. Contact for Scientific Queries	Overall Study Officials
9. Public Title	Brief Title
10. Scientific Title	Official Title
11. Countries of Recruitment	Facility Information - Country
12. Health Condition(s) or Problem(s) Studied	Primary Disease or Condition Being Studied in the Trial, or the Focus of the Study
13. Intervention(s)	Intervention Type, Intervention Name(s), Intervention Description, Arm or Group/Interventional Cross- Reference, Arm Title, Arm Type, Arm Description
14. Key Inclusion and Exclusion Criteria	Eligibility Criteria, Sex/Gender, Age Limits, Accepts Healthy Volunteers
15. Study Type	Study Type, Allocation, Masking, Interventional Study Model, Primary Purpose, Study Phase
16. Date of First Enrollment	Study Start Date
17. Sample Size	Enrollment
18. Recruitment Status	Overall Recruitment Status
19. Primary Outcome(s)	Primary Outcome Measure Information - Title, Description, Time Frame
20. Key Secondary Outcomes	Secondary Outcome Measure Information - Title, Description, Time Frame
21. Ethics Review	Human Subjects Review
22. Completion Date	Study Completion Date
23. Summary Results	ClinicalTrials.gov Results Data Elements
24. IPD Sharing Statement	IPD Sharing Statement – *"Plan to Share IPD: Yes" or "Plan to Share IPD: No" required by ICMJE*

Table 1: WHO 24-item requirement list

Appendix I: Trial registration

ClinicalTrials.gov PRS
Protocol Registration and Results System

ClinicalTrials.gov PRS DRAFT Receipt (Working Version)
Last Update: 09/20/2021 14:00

ClinicalTrials.gov ID: NCT05056220

Study Identification

Unique Protocol ID:	ALBTRIALv1.1
Brief Title:	Personalized Long-term Human Albumin Treatment in Patients With Decompensated Cirrhosis and Ascites
Official Title:	A 26-Week Randomized Multicentre, Double-Blinded and Placebo-Controlled, Clinical Trial of Human Albumin in the Treatment of Decompensated Cirrhosis Guided by the MICROB-PREDICT Biomarker
Secondary IDs:	825694 [Grantor or Funder: HORIZON 2020]

Study Status

Record Verification:	September 2021
Overall Status:	Not yet recruiting
Study Start:	June 2022 [Anticipated]
Primary Completion:	September 2024 [Anticipated]
Study Completion:	October 2024 [Anticipated]

Sponsor/Collaborators

Sponsor:	Aleksander Krag
Responsible Party:	Sponsor-Investigator Investigator: Aleksander Krag [akrag] Official Title: Professor Affiliation: Odense University Hospital
Collaborators:	EASL - CLIF Consortium

Oversight

U.S. FDA-regulated Drug:	No
U.S. FDA-regulated Device:	No
U.S. FDA IND/IDE:	No
Human Subjects Review:	Board Status: Not yet submitted
Data Monitoring:	

Study Description

Brief Summary:	ALB-TRIAL

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Detailed Description: NOTE : Detailed Description has not been entered.

Conditions

Conditions: Decompensated Cirrhosis and Ascites

Keywords:

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 4

Interventional Study Model: Parallel Assignment

Number of Arms: 4

Masking: Triple (Participant, Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 240 [Anticipated]

Arms and Interventions

Arms	Assigned Interventions
Active Comparator: High expected effect: Human Albumin 20% + Standard Medical Treatment	Drug: Human albumin 20%
Placebo Comparator: High expected effect: NaCl 0.9% + Standard Medical Treatment	Drug: sodium chloride 0.9%
Active Comparator: Low expected effect: Human Albumin 20% + Standard Medical Treatment	Drug: Human albumin 20%
Placebo Comparator: Low expected effect: NaCl 0.9% + Standard Medical Treatment	Drug: sodium chloride 0.9%

NOTE : Arm Description has not been entered.
NOTE : Arm Description has not been entered.
NOTE : Arm Description has not been entered.
NOTE : Arm Description has not been entered.
NOTE : Intervention Other Names have not been specified
NOTE : Intervention Other Names have not been specified

Outcome Measures

Primary Outcome Measure:

1. Cumulative number of liver-related clinical outcomes
   [Time Frame: 6 months]

NOTE : Outcome Measure Description has not been entered.

Eligibility

Minimum Age: 18 Years

Maximum Age:	
Sex:	All
Gender Based:	No
Accepts Healthy Volunteers:	No
Criteria:	Inclusion Criteria: - ... Exclusion Criteria: - ...

Contacts/Locations

Central Contact Person:	Aleksander Krag, Professor Telephone: +4566113333 Email: aleksander.krag@rsyd.dk
Central Contact Backup:	Jonel Trebicka, Professor Email: jonel.trebicka@kgu.de
Study Officials:	Aleksander Krag, Professor Study Principal Investigator Odense University Hospital
Locations:	**Denmark** Odense University Hospital Odense, Denmark, 5000 **Germany** Universitätsklinikum Frankfurt Frankfurt, Germany, 60590 Contact: Jonel Trebicka

IPDSharing

Plan to Share IPD:	

References

Citations:	
Links:	
Available IPD/Information:	

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

3. Acknowledgement and Disclaimer

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