GALAXY

GUT-AND-LIVER AXIS IN ALCOHOLIC LIVER FIBROSIS
GRANT NUMBER 668031

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DOCUMENT MAIN AUTHORS: Suganya Jacobsen, research fellow, Maja Thiele, WP 1 Leader, OUH
DOCUMENT SIGNED OFF BY: Project manager Louise Skovborg Just (University of Southern Denmark)

1. AIMS

D1.6 Approvals obtained for SYN-ALD

1. Written study protocol to be used for study execution and applications to the GCP unit, ethics committee and Danish data protection agency.
2. Approvals in writing from the GCP unit, ethics committee and Danish data protection agency.

2. RESULTS

The first version of the SYN-ALD Study protocol was completed and approved by the Regional Ethics Committee for Southern Denmark by November 2017 under ethical id S-20170163. Due to changes in study design we revised the study protocol and submitted a supplement to the regional Ethics Committee the 18th of January 2019. This supplement was approved on February 18th.
The ethically approved study protocol also includes appendices with participant information and instructions, a layman summary, standard operational procedures for all our applied methods and standard questionnaires.
As neither Profermin® nor Fresubin® are registered as medicaments, but rather fodds for medical purposes, Good Clinical Practice (GCP) monitoring was not needed for the study.

We applied for approval of patient data administration to the Danish Data Protection Agency in January 2019; they approved the study on February 8th 2019 under journal number 19/6646.

SYN-ALD have been registered at clinicaltrials.gov since 4th of March 2019 under the identifier NCT03863730.