

# Efficacy and Safety of Oral Controlled-release Nicotinic Acid (CIR-NA) for the Remission of Prediabetes. (CONCEPT)

NCT07286747

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Status	RECRUITING
Phase	Phase 2
Sponsor	University Hospital Schleswig-Holstein
Enrollment	390 participants

## Key Eligibility Criteria

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### Inclusion (6)

- Male and female participants e 18 to < 80 years of age (at the time of signing the informed consent).
- Body mass index e 20 kg/m<sup>2</sup>.
- Ability to understand and comply with the protocol.
- Signed written informed consent.
- Diagnosed prediabetes according to the current EASD/DDG guidelines. Prediabetes is present if at least one value is in the prediabetes range, but no value is in the T2DM range.
- ... and 1 more (see full listing online)

### Exclusion (20)

- Presence or a history of type 2 diabetes mellitus according to the current EASD/DDG guidelines.
- Participants with relevant medical conditions (based on evaluation of medical history and screening assessments), unstable and uncontrolled underlying diseases, e.g., hypothyroidism, asthma, COPD or arterial hypertension, can be excluded per judgment of the Investigator.
- Renal impairment (glomerular filtration rate <60 ml/min/1.73).
- Impairment of hepatic function (one or more of liver enzymes alanine transaminase, aspartate transaminase and gamma glutamyl transferase > 3-fold compared to normal range).
- Current infection with hepatitis B or C.
- ... and 15 more (see full listing online)

## Locations (2 total)

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University Medical Center Schleswig-Holstein, Campus Kiel, Kiel, Germany  
University of Leipzig Medical Center, Leipzig, Germany