

# Combined retrospective/prospective epidemiological trial

<b>Submission date</b> 22/09/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 23/02/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 05/11/2009	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
N/A

# Study information

## Scientific Title

## Acronym

Pankcourse

## Study objectives

The course of the disease (symptoms, progression) in patients with chronic pancreatitis seems to depend on the etiology of disease. The trial observes and compares different entities of chronic pancreatitis especially concerning alcoholic and non-alcoholic development but also with stratification after different genetic mutations.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Ethics committee of Leipzig University (ref: 160/2004)

## Study design

Combined retrospective/prospective epidemiological trial

## Primary study design

Observational

## Secondary study design

Other

## Study setting(s)

Not specified

## Study type(s)

Not Specified

## Participant information sheet

## Health condition(s) or problem(s) studied

Chronic pancreatitis

## Interventions

Combined retrospective/prospective epidemiological trial with retrospective and five-year prospective observation using questionnaires on symptoms concerning chronic pancreatitis

## Intervention Type

Other

## Phase

Not Specified

**Primary outcome measure**

Course of disease

**Secondary outcome measures**

1. Age of first manifestation
2. Calcification at first manifestation
3. Time until development of endocrine and exocrine dysfunction
4. Pain and inflammatory episodes
5. Development of complication as pancreatic duct stenosis

**Overall study start date**

01/05/2001

**Completion date**

01/05/2004

**Eligibility****Key inclusion criteria**

Patients with chronic pancreatitis with written informed consent

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

200 patients with non-alcoholic, 100 with alcoholic pancreatitis

**Key exclusion criteria**

1. Uncured cancer within last five years
2. Radiation and chemotherapy within last five years
3. Other disorders causing abdominal pain such as chronic inflammatory bowel disease, irritable bowel disease and chronic ulcer disease

**Date of first enrolment**

01/05/2001

**Date of final enrolment**

01/05/2004

**Locations****Countries of recruitment**

Germany

**Study participating centre**  
**Ph.-Rosenthalstr. 27**  
Leipzig  
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04103

## **Sponsor information**

**Organisation**  
University of Leipzig (Germany)

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**Sponsor type**  
University/education

**ROR**  
<https://ror.org/03s7gtk40>

## **Funder(s)**

**Funder type**  
University/education

**Funder Name**  
University of Leipzig (Germany)

## **Results and Publications**

**Publication and dissemination plan**  
Not provided at time of registration

**Intention to publish date**

## **Individual participant data (IPD) sharing plan**

### **IPD sharing plan summary**

Not provided at time of registration