

# Randomised, controlled, double-blind trial of Chinese Herbal Medicine as adjuvant treatment in patients with Crohn's disease

<b>Submission date</b> 29/05/2002	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 29/05/2002	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 16/04/2009	<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**  
CHM-Crohn

# Study information

## Scientific Title

## Acronym

CHM-Crohn

## Study objectives

Not provided at time of registration.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Not provided at time of registration.

## Study design

Randomised controlled trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Not specified

## Study type(s)

Not Specified

## Participant information sheet

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

Crohn's disease

## Interventions

1. Chinese Herbal Medicine Preparation (capsuled pulverised Chinese Medicinal Recipe; 11 drugs) to be taken for 12 weeks; 9 g daily
2. Placebo (identical in taste and flavour); 12 weeks, 9 g daily

## Intervention Type

Other

## Phase

Not Specified

## Primary outcome measure

Not provided at time of registration.

**Secondary outcome measures**

Not provided at time of registration.

**Overall study start date**

01/04/2000

**Completion date**

30/04/2002

## Eligibility

**Key inclusion criteria**

1. 60 participants
2. Disease duration greater than 1 year
3. Crohn's Disease Activity Index (CDAI) 150 - 450
4. Aged 18 - 60 years

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

60

**Key exclusion criteria**

Not provided at time of registration.

**Date of first enrolment**

01/04/2000

**Date of final enrolment**

30/04/2002

## Locations

**Countries of recruitment**

Germany

**Study participating centre**

Krankenhausstrasse 12  
Erlangen  
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## Sponsor information

### Organisation

Friedrich-Alexander-University of Erlangen-Nuremberg (Germany)

### Sponsor details

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### Sponsor type

University/education

### Website

<http://www.uni-erlangen.org/>

### ROR

<https://ror.org/00f7hpc57>

## Funder(s)

### Funder type

Research organisation

### Funder Name

Rut- and Klaus-Bahlsen-Foundation (Germany)

### Funder Name

University Hospital of Erlangen (Germany) - Erlanger Leistungsbezogene Anschubfinanzierung und Nachwuchsförderung (ELAN) fund

## 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