

# ICAD: Clinical validation study of a new algorithm for oral anticoagulant dosing

<b>Submission date</b> 26/09/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 26/09/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 08/09/2008	<b>Condition category</b> Haematological Disorders	<input type="checkbox"/> Individual participant data

**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**  
P02-089; NTR724

# Study information

## Scientific Title

## Acronym

ICAD

## Study objectives

The equations used by most current algorithms are usually based on a simple pharmacodynamic model, which implies a linear function between the international normalised ratio (INR) and the dosage. Our new algorithm consists of two sub-models in which the first sub-model describes the collective influence of all processes on the effect of the vitamin K antagonist and the second sub-model describes the relationship between the dosage and the corresponding INR. The second sub-model includes a variable parameter to reflect the sensitivity of the patient that may change over time. Because of the inclusion of a parameter that reflects the sensitivity of the patient we think it is better capable of proposing a dosage that leads to an INR within the therapeutic range.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Ethics approval received from the local medical ethics committee

## Study design

Randomised controlled trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Not specified

## Study type(s)

Diagnostic

## Participant information sheet

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

Anticoagulant treatment

## Interventions

Oral anticoagulant dosage supported by the new algorithm (ICAD) and oral anticoagulant dosage supported by the standard algorithm (TRODIS).

## Intervention Type

Other

## **Phase**

Not Specified

## **Primary outcome measure**

1. Percentage of time therapeutic range
2. Proportion of visits in which the algorithm gave a proposal
3. Proportion that was accepted by the physician

## **Secondary outcome measures**

1. Mean time between visits
2. Bleeding events
3. Thrombotic events

## **Overall study start date**

14/08/2003

## **Completion date**

01/09/2004

# **Eligibility**

## **Key inclusion criteria**

1. Indication for long term anticoagulant therapy
2. Aged between 18 and 80

## **Participant type(s)**

Patient

## **Age group**

Adult

## **Lower age limit**

18 Years

## **Sex**

Both

## **Target number of participants**

712

## **Key exclusion criteria**

1. Participation in the patient self-management program
2. Staying long periods abroad
3. Terminal stage of disease

## **Date of first enrolment**

14/08/2003

**Date of final enrolment**

01/09/2004

## Locations

**Countries of recruitment**

Netherlands

**Study participating centre**

**Leiden University Medical Center (LUMC)**

Leiden

Netherlands

2300 RC

## Sponsor information

**Organisation**

Leiden University Medical Center (LUMC) (The Netherlands)

**Sponsor details**

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P.O. Box 9600

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**Sponsor type**

Hospital/treatment centre

**ROR**

<https://ror.org/05xvt9f17>

## Funder(s)

**Funder type**

Industry

**Funder Name**

Foundation Basis (now known as iSOFT) (The Netherlands)

**Funder Name**

Dutch Thrombosis Foundation (The Netherlands)

## 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

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	Results	01/05/2005		Yes	No