

Vague Medical Problems In REsearch (VAMPIRE): Blood test ordering for unexplained complaints in general practice.

Submission date 22/11/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 22/11/2005	Overall study status Completed	<input checked="" type="checkbox"/> Protocol
Last Edited 18/03/2009	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

Blood test ordering for unexplained complaints in general practice

Acronym

VAMPIRE

Study objectives

1. When patients visit their GPs with unexplained complaints it is cost effective to follow a watchful waiting strategy of four weeks before ordering laboratory tests
2. A systematically developed quality improvement strategy, based on barriers and facilitators of GPs' blood test ordering behaviour, is cost effective in supporting GPs to postpone blood test ordering

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the Medical Ethics Committees of:

1. The Academic Medical Center-University of Amsterdam
2. The University Hospital Maastricht

Study design

Multicentre randomised single blind parallel group controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

GP practice

Study type(s)

Diagnostic

Participant information sheet

Health condition(s) or problem(s) studied

Unexplained complaints

Interventions

1. Immediate blood test ordering versus watchful waiting of 4 weeks with blood test ordering after four weeks only if complaints remain
2. Quality improvement strategy consisting of small group meetings, practice visits, patient leaflets and waiting room videotape versus no quality improvement strategy

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

1. Accuracy of blood tests for serious pathology (per test and in combinations relevant for general practice), related and in addition to signs and symptoms, at the moment of presentation and after postponing test ordering for four weeks
2. Adherence of GPs to instruction either to order blood tests directly or after a watchful waiting policy of four weeks

Secondary outcome measures

1. Incidence of unexplained complaints in general practice
2. Predictive value of GPs' working hypothesis
3. Duration of unexplained complaints
4. Effect of unexplained complaints on quality of life of patients
5. Effect of direct testing or watchful waiting on satisfaction with care, anxiety, medical consumption and absence from work of patients
6. Effect of direct testing or watchful waiting on satisfaction, anxiety and insecurity of GPs
7. Effect of quality improvement intervention on knowledge about the value of blood test ordering in unexplained complaints, communication skills and attitudes of GPs
8. Barriers to and facilitators of proposing a watchful waiting strategy by GPs
9. Costs of the quality improvement intervention

Overall study start date

01/01/2002

Completion date

31/12/2004

Eligibility**Key inclusion criteria**

1. Patients of 18 years and above with:
 - 1.1. Unexplained fatigue
 - 1.2. Abdominal complaints
 - 1.3. Musculoskeletal complaints
 - 1.4. Weight changes
 - 1.5. Itching
2. Patients have not contacted their GPs for the last six months with the same complaints
3. Patients able to speak, read and write Dutch

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

5000

Key exclusion criteria

The GP is worried that the patient has got serious pathology that makes watchful waiting unacceptable.

Date of first enrolment

01/01/2002

Date of final enrolment

31/12/2004

Locations**Countries of recruitment**

Netherlands

Study participating centre

Maastricht University

Maastricht

Netherlands

6200 MD

Sponsor information**Organisation**

Care and Public Health Research Institute (CAPHRI) (Netherlands)

Sponsor details

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Sponsor type

Research organisation

Website

<http://www.caphri.nl/>

ROR

<https://ror.org/02jz4aj89>

Funder(s)

Funder type

Research organisation

Funder Name

Central Sickfund (CZ) health care insurance (Netherlands)

Funder Name

The Netherlands Organization for Scientific Research (NWO) (Netherlands)

Funder Name

Dutch Health Care Insurance Board (CVZ, independent government organisation) (Netherlands)

Funder Name

Stichting 'De drie Lichten' (Netherlands)

Funder Name

Dutch Heart Foundation (Netherlands)

Alternative Name(s)

Heart Foundation

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

Netherlands

Funder Name

Stichting Volksgezondheid en Roken (STIVORO) (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?
Protocol article	protocol	22/03/2006		Yes	No
Results article	results	01/03/2009		Yes	No