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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

Registration date
22/11/2005

Overall study status
Completed

Last Edited
18/03/2009

Condition category
Mental and Behavioural Disorders

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

NTR398

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