

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

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29137

Source

NTR

Brief title

VAMPIRE

Health condition

Unexplained complaints: those complaints in which the GP, after clarifying the reason for encounter, history taking and performing physical examination cannot establish a diagnosis.

Sponsors and support

Primary sponsor: a. University of Maastricht, Care and Public Health Research Institute (CAPHRI), Department of General Practice.

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b. Academic Medical Center - University of Amsterdam, Division of Clinical Methods & Public Health, Department of General Practice

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Source(s) of monetary or material Support: Dutch College of Health Care Insurances (CVZ)

Central Sickfund (CZ) health care insurance

Netherlands Organisation of Scientific Research (NWO) (AGIKO stipend)

Stichting 'De drie Lichten'

Stichting Volksgezondheid en Roken (STIVORO)

Nederlandse Hartstichting

Intervention

Outcome measures

Primary outcome

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

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.

Study description

Background summary

Title:

'Blood test ordering for unexplained complaints in general practice (VAMPIRE)'

Objectives:

to determine the course of unexplained complaints, to determine the accuracy of (combinations of) diagnostic tests, including signs symptoms and contextual factors in patients presenting with unexplained complaints, to determine the cost-effectiveness of a watchful waiting strategy of a month compared to direct blood test ordering, to systematically design a quality improvement strategy for GPs aiming at postponement of blood test ordering in patients with unexplained complaints, to determine the cost-effectiveness of this quality improvement strategy.

Design:

on GP level randomised clinical trial with three arms. GPs in arm 1 order blood tests immediately, GPs in arm 2 suggest a watchful waiting strategy of four weeks and order blood tests only when complaints persist, GPs in arm 3 also postpone blood test ordering but are also supported by a systematically developed quality improvement strategy. Follow-up of patients is one year. A delayed type cross sectional study is performed to establish a diagnosis after a year.

Study objective

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.

Study design

N/A

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

1. Patients of 18 years and above with unexplained fatigue;
2. Abdominal complaints;
3. Musculoskeletal complaints;
4. Weight changes or itching
who have not contacted their GPs for the last six months with the same complaints

and are able to speak, read and write Dutch.

Exclusion criteria

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

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2002
Enrollment:	5000
Type:	Actual

Ethics review

Positive opinion	
Date:	13-09-2005
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL359
NTR-old	NTR398
Other	: N/A
ISRCTN	ISRCTN55755886

Study results

Summary results

BMC Fam Pract. 2006 Mar 22;7:20.

1. van Bokhoven MA, van der Weijden T, Dinant G-J. Challenges in the methodology of diagnostic research on patients presenting with unexplained complaints in general practice. J Clin Epidemiol, accepted for publication.

2. Koch H, Meerkerk GJ, Zaat JO, Ham MF, Scholten RJ, Assendelft WJ. Accuracy of carbohydrate-deficient Transferrine in the detection of excessive alcoholconsumption: a systematic review. Alcohol 2004;39:75-85.

3. van Bokhoven MA, Kok G, van der Weijden T. Designing a quality improvement intervention: a systematic approach. Qual Saf Health Care 2003;12:215-220.
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4. van der Weijden T, van Bokhoven MA, Dinant GJ, van Hasselt CM, Grol RP. Understanding laboratory testing in diagnostic uncertainty: a qualitative study in general practice. Br J Gen Pract 2002;52:974-80.
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5. Dinant GJ, van Wijk MAM, Janssens HJEM et al. Dutch College of General Practitioners guideline 'Blood testing. General principles and use under direct management. [NHG-standaard bloedonderzoek. Algemene principes en uitvoering in eigen beheer]. Huisarts Wet 1994;37:202-211.