

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

Gepubliceerd: 13-09-2005 Laatste bijgewerkt: 18-08-2022

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...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON29137

Bron

Nationaal Trial Register

Verkorte titel

VAMPIRE

Aandoening

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

Ondersteuning

Primaire 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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Overige ondersteuning: 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

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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;
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2. Adherence of GPs to instruction either to order blood tests directly or after a watchful waiting policy of four weeks.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type: Interventie onderzoek
Onderzoeksmodel: Parallel

Toewijzing:	Gerandomiseerd
Blinding:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	01-01-2002
Aantal proefpersonen:	5000
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies	
Datum:	13-09-2005
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten

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.