Effectiveness of adding additional tests and/or comments to laboratory reports in a patient population, referred by general practitioners to the clinical chemistry laboratory.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23047

Source
Nationaal Trial Register

Brief title
N/A

Health condition

As the procedure involves the inspection of all (abnormal) reports by a laboratory specialist, all related diseases will be subject to this investigation.

Sponsors and support

Primary sponsor: Dr. Wytze P. Oosterhuis
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Source(s) of monetary or material Support: SKMS (VAL) project nr. 4123039 (Richtlijn Feedback eerste lijn) en 4123579 (Evidence based medicine bij laboratoriumdiagnostiek)

Intervention

Outcome measures

Primary outcome

In every case where a report with comments is generated (both in control and study groups), the following data will be collected:

1. Following laboratory reports;

2. Following treatments, referrals;

3. Other additional diagnostic procedures and patient data from the general practitioner.

Secondary outcome

A panel (consisting of medical specialists) will be asked to answer the following questions:

1. How useful were the additional tests and comments for the patient?;

2. What was the benefit for the patient in terms of health improvement?;

3. Was the treatment adequate in the control group, without additional information reported to the general practitioner? This will be graded from negative to positive.

Study description

Background summary

Reflective testing is not a routine in the Netherlands. It is common practice in the UK, where such post-analytical processing is integral to the provision of a quality service, and as such is a requirement for laboratory accreditation there. However, evidence of the effectiveness of this procedure is very limited. In the present situation, the laboratories in the Netherlands do deliver extra services additional to reporting of test results. It is common practice to report strongly abnormal results directly by phone to the physician. In some special test procedures (e.g. bone marrow investigation, flow cytometry, hemoglobinopathies) the laboratory professional is more involved in the diagnostic procedure, and test results are supplemented with an interpretative comment. Reflective testing would add a new dimension to the service of the clinical chemistry laboratory to primary health care. It is a potential powerful tool for completing the diagnostic process.

Most of the reports of patients in general practice do not have abnormal test results, or have

minor abnormal results not needing special attention. About 15 % of the reports do have abnormal results that need the attention of a laboratory professional. About 3 % of all reports are subject to reflective testing.

The goal of this project is the investigation of the effectiveness of reflective testing (the intervention: adding additional test results and/or comments to the test report) compared with routine care (the traditional report, without additional testing or comments being sent to the general practitioner), in a patient population referred by general practitioners to the clinical chemistry laboratory.

Study objective

The goal of this project is the investigation of the effectiveness of reflective testing (the intervention: adding additional test results and/or comments to the test report) compared with routine care (the traditional report, without additional testing or comments), in a patient population, referred by general practitioners to the clinical chemistry laboratory.

Study design

Measurements will be done after a follow-up period of 6 months.

Intervention

Study design: a randomised clinical trial with reports with reflective testing vs. traditional reports. The randomisation of reports will be performed after the laboratory specialist has done the additional testing and commenting. All selected laboratory results will be subject to reflective testing but only in half of the cases the general practitioners will receive the report. After a follow-up period of 6 months, the differences in diagnostic and therapeutic actions of the general practitioners will be investigated.

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Eligibility criteria

Inclusion criteria

The study will be restricted to those cases, in which abnormal test results require additional testing and/or comments, according to the laboratory specialist.

Exclusion criteria

Cases in which there is substantial risk for the patient and normally (following the existing protocol) the lab would either send an urgent fax message to the practice or the laboratory specialist would directly make a telephone call to the general practitioner.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-09-2009
Enrollment:	400
Type:	Anticipated

Ethics review

Positive opinion Date:	21-07-2009
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	NL1817
NTR-old	NTR1927
Other	METC Atrium Medisch Centrum, Orbis Medisch en Zorgconcern en Hogeschool Zuyd : 08-N-73
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A