

## TRIAL INFO

### What are the effects of internal audits on quality and safety of hospital care?

- KANDIDAAT NUMMER	11316
- NTR NUMBER	<b>NTR3343</b>
- ISRCTN	ISRCTN wordt niet meer aangevraagd.
- DATUM ISRCTN	
- DATUM AANVRAAG ISRCTN	
- REGISTRATIE DATUM NTR	12-mrt-2012
- SECONDARY IDS	2011/278 METC Radboud University Nijmegen Medical Centre
- KORTE TITEL VAN DE STUDIE	What are the effects of internal audits on quality and safety of hospital care?
- WETENSCHAPPELIJKE TITEL	The effects of auditing on patient safety in hospital care: Results in a Dutch hospital at ward level.
- ACRONYM	APS study = Audit Patient Safety study
- HYPOTHESE	The objective of this thesis is to get insight into the effects of internal audits on patient safety and on health care professional's behavior in an academic hospital at ward level.
- AANDOENING(EN)	<b>Patientveiligheid, Ziekenhuis zorg, Interne toetsing</b>
- INCLUSIE CRITERIA	The included departments of the Radboud University Nijmegen Medical Centre are: 1. Comprehensive and thus recognizable for other hospitals; 2. Delivering clinical care with basic risks for patient safety; 3. Will be audited between October 2011 and February 2013.
- EXCLUSIE CRITERIA	In this study we exclude the following criteria: 1. The eight 'sub audits' perform by experts (Medication Safety, Hygiene and Infection prevention, ARBO and milieu, Medical Devices, Sterile Medical Aids, Patient-centered, Education and Scientific Research); 2. Departments which facilitating healthcare processes to clinical and outdoor patients, for example Radiotherapy, Operating Rooms and Laboratory Medicine; 3. The safety of outpatients.
- MEC GOEDKEURING VERKREGEN?	ja
- MULTICENTER ONDERZOEK	nee
- GERANDOMISEERD	nee
- GROUP	Parallel
- TYPE	Single arm
- STUDYTYPE	observationeel
- BEOEGDE STARTDATUM	15-aug-2011
- BEOEGDE EINDDATUM	1-jan-2015

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Wie zijn wij?

Waarom registreren?

Aanmelden voor registratie

Online registreren

Inloggen voor aanmelden trial

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NRT en CCMO

Contact

ENGLISH

INTERNATIONALE  
OPENBARE  
REGISTERS

MetaRegister  
van CCT (UK)

ISRCTN-Register  
van CCT (UK)

- BEOOGDE AANTAL DEELNEMERS	800
- INTERVENTIES	Internal audits.
- PRIMAIRE UITKOMST	Complications and adverse events.
- SECUNDAIRE UITKOMST	<ol style="list-style-type: none"> <li>1. Patient safety culture;</li> <li>2. Team Climate;</li> <li>3. Experiences of patients;</li> <li>4. Standardized Mortality Rate (SMR);</li> <li>5. Unintended prolonged hospital stay;</li> <li>6. Learning effects of health care givers and department leaders.</li> </ol>
- TIMEPOINTS	<p>Primary outcome: Complications and adverse events in hospital care are measured by structured retrospective patient record review of hospital admissions 3 months before and 15 months after an internal audit.</p> <p>Secundairy outcomes:  <ol style="list-style-type: none"> <li>1. The patient safety culture within a team of health care givers is measured by the Dutch Questionnaire COMPaZ 3 months before and 15 months after an internal audit;</li> <li>2. The team climate is determined by the Team Climate Inventory 3 months before and 15 months after an internal audit;</li> <li>3. Patients experiences with hospital care are measured with the Consumer Quality Index of Hospital Admission 3 months before, 9 and 15 months after an internal audit;</li> <li>4.+ 5. The SMR and the data of unintended prolonged hospital stay are derived monthly from the hospital registry database and the national medical registration (LMR);</li> <li>6. The learning effects of health care givers and department leaders are gathered retrospective by in-depth questionnaires and for this study developed questionnaires.</li> </ol> </p>
- TRIAL WEB SITE	N/A
- STATUS	open: actieve patiënten inclusie
- CONTACT, VOOR ALGEMENE VRAGEN	<a href="#">Mirelle Hanskamp-Sebregts</a>
- CONTACT, VOOR WETENSCHAPPELIJKE VRAGEN	<a href="#">PhD. Marieke Zegers</a>
- SPONSOR/INITIATOR (E.G. UNIVERSITY MEDICAL CENTER)	<a href="#">Radboud University Nijmegen Medical Centre</a>
- FONDS(EN)	<a href="#">Radboud University Nijmegen Medical Centre</a>
- PUBLICATIES	N/A
- KORTE SAMENVATTING	<p>We examine the current internal audits of the Radboud University Nijmegen Medical Centre; are they a valid, reliable and responsive diagnostic instrument to analyze the safety of patient care? And we want to know what the results of the internal audits of the Radboud University Nijmegen Medical Centre are on the safety of patient care in (academic) hospitals. We use a mix method approach (quantitative and qualitative research methods) to measure the effects of internal audits on different levels: patient, professional and department level. To measure the effects of internal audits on patient safety in clinical hospital care we use a before-and-after design. The null hypothesis is that there is no difference of patient safety of healthcare between the measurement before and after the internal audit and between departments with and without an internal audit. The</p>

alternative hypothesis is that internal audits improve the patient safety of healthcare in the Radboud University Nijmegen Medical Centre. In this study we perform a determinant analysis to correct statistical for potential confounders. And we also perform a process analysis to explain certain (un)expected effects of internal audits. This study takes place in the Netherlands.

- BELANGRIJKSTE WIJZIGINGEN  
(AUDIT TRAIL)

- RECORD 12-mrt-2012 - 29-mrt-2012

- Indien u gegevens wilt toevoegen of veranderen, kunt u een mail sturen naar [nederlands@trialregister.nl](mailto:nederlands@trialregister.nl)