


[Home](#) | [Login](#) | [Contact us](#) | [Feedback](#)

Australian Clinical Trials Registry

[Register Trial](#) | [Trial Search](#) | [Latest News](#) | [FAQ](#) | [About ACTR](#)

International Committee
of Medical Journal
Editors (ICMJE): May
2005 editorial

International Committee
of Medical Journal
Editors (ICMJE):
October 2004 editorial
response

International Committee
of Medical Journal
Editors (ICMJE):
September 2004
editorial

WHO International
Clinical Trials Registry
Platform (ICTRP)

NHMRC Clinical Trials
Centre

National Health and
Research
Council (NHMRC)
information about the
ACTR

Frequently Asked
Questions about the
ACTR

About the ACTR

How to register a trial

Trial Details

Request Number: 001490
ACTR Number: ACTRN012606000338561
Trial Status: Registered
Date Submitted: 26/07/2006
Date Registered: 8/08/2006

Title: **Evaluation of the Medex Test for the Detection of Gastrointestinal Disorders**

Official scientific title: **Evaluation of the Medex Test for the Detection of Gastrointestinal Disorders**

Secondary IDs: **Nil**

Trial acronym:

Condition: **Gastrointestinal Disorders**

Condition code:

Intervention/s: **The MEDEXTEST device is intended to differentiate between normal and abnormal function of the stomach and duodenum. The MEDEXTEST is a non-invasive radiation free device. The examination lasts approximately 20 minutes and is performed in the following manner:**

1. External measurement of 24 skin zones located on the limbs.
2. Stimulation of four special skin zones – lasting one minutes each.
3. External measurement of the same 24 zones.

The study design is blind, one-armed, comparative, prospective and without a control group. The examination is only conducted once.

Diagnosis

The primary objective is to determine the sensitivity, specificity and total accuracy of the device through it's ability to accurately and effectively diagnose:

1. Disorders of the stomach and duodenum due to Gastritis, Gastroduodenitis, Peptic Ulcer Disease, Gastric Cancer and other causes.

2. Type of disease

Assuming true sensitivity and specificity of 0.90, the criteria for the study success will be observing sensitivity and specificity of above 0.80 at a confidence interval of 97.5.

The primary outcomes will be measured and evaluated at the completion of the MEDEXTEST and other investigations (EGD with or without biopsy and Urea Breath Test) on all 200 study participants.

Key secondary outcome/s: **The secondary objective is to evaluate the technical intra-device variability between Medex Test devices.**

The observed sensitivity and specificity of the MEDEXTEST in -between study subgroups (age, gender and type of disease) is expected to be of no significant difference.

The observed sensitivity and specificity of the MEDEXTEST intra -device variability is expected to be of no significant difference.

The secondary outcome will be measured and evaluated at the completion of the MEDEXTEST and other investigations (EGD with or without biopsy and Urea Breath Test) on all 200 study participants.

Key inclusion and exclusion criteria: **200 male and female outpatients with clinical symptoms of active digestive disease will be enrolled into the study. The recruitment process of study participants will assure that the baseline characteristics (age, BMI and gender) will be similar. Patients must be over 18 years of age to be eligible for recruitment to study. Exclusion criteria include those patients who are amputees, pregnant or suffering form local skin damage in the areas of Medex Test examination.**

Study type: **Interventional**

Purpose of the intervention: **Diagnosis**

Allocation to intervention: **Nonrandomized trial**
 Allocation concealment:
 Sequence generation:
 Masking: **Double blind**
 Control group: **Uncontrolled**
 Assignment: **Single group**
 Other design features (specify): **All physicians and technicians will be blind to each others examination and MEDEXTEST findings.**
 Endpoint: **Safety/efficacy**

Phase

Anticipated trial start date: **31/07/2006**
 Target sample size: **200**
 Recruitment status (at time of registration): **Open to recruitment**
 Funding source/s: **Medex Screen (AustralAsia) Pty Ltd**
 Primary sponsor: **Medex Screen (AustralAsia) Pty Ltd**
 Secondary sponsor/s: **NONE**
 Has the study received appropriate ethics committee approval review: **Yes**
Site/s with ethics approval: **Sydney West Area Health Service Human Research Ethics Committee - Nepean Campus**

Approval date: 6th June 2006

HREC identification number: 06/003

Brief summary:

The primary objective is to compare findings achieved by traditional diagnostic procedures with those of the MEDEXTEST in order to define specificity, sensitivity and accuracy of the MEDEXTEST device. Traditional diagnostic procedures include an evaluation by a physician (history and physical examination), Esophagogastroduodenoscopy (EGD) with/without biopsy and Urea Breath Test.

The study population will include 200 male and female patients with clinical symptoms of gastroduodenal disorders of similar baseline characteristics (age, BMI and gender). Investigators and Gastroenterologists at Nepean Hospital will refer patients. Eligibility will be determined by satisfying the following inclusion and exclusion criteria.

Eligible participants will undergo a baseline evaluation, which includes: written consent, demographic information, medical history, current medications and a physical examination. Participants will undergo the 20-minute MEDEXTEST conducted by a trained Research Assistant. They will be advised of their results at an appointment with their physician following their endoscopy procedure. The participants will be referred to tests according to clinical and examination findings such as an Esophagogastroduodenoscopy (EGD) (with or without biopsy) and Urea Breath Test.

The MEDEXTEST is a non-invasive examination lasting approximately 20 minutes in duration and performed in the following manner:
 - External measurement of the skin's electrical resistance of 24 zones located on the participant's feet and hands.
 - T.E.N.S stimulation.
 - A repeated measurement of the 24 zones.
 - Mathematical processing of the collected information by the help of a previously composed correlative algorithm.
 - The results will be saved in the operator's computer memory and, additionally, a printout will be filed in the patient's source documentation file.

At the completion of data collection, a trained physician will make an independent reading from the MEDEXTEST results, with another physician diagnosing the participant based on the traditional procedures. To minimize the risk of bias, all physicians will be blind to their colleague's diagnosis. A third investigator will compare the diagnosis from the traditional diagnostic procedures against the MEDEXTEST, record test results in participants' CRF and conduct a follow-up consultation with participant. After the required data is obtained from all study participants of the study site, the results of the MEDEXTEST will be compared with the actual participant's condition as indicated by the traditional tests, in order to determine the sensitivity, specificity and total accuracy of the device. The estimated duration of the study is 1 year including data analysis and reporting.

Responsible contact person
 Name:

Johel Neiron

Address: **Medex Screen (AustralAsia) Pty Ltd**
Unit 5
20 Twickenham Rd
Burswood WA 6100
Australia

Tel: **+61 8 94721184**

Fax: **+61 8 94703836**

Email: **johel@medexaus.com**

Research contact person

Name: **Associate Professor Martin Weltman**

Address: **Nepean Hospital**
PO Box 63
Penrith NSW 2751
Australia

Tel: **+61 2 47343332**

Fax: **+61 2 47343145**

Email: **weltmam@wahs.nsw.gov.au**

[Print trial details](#) 

© 2005 ACTR [Terms and Conditions](#) [Privacy](#) [Design by Symbiation](#)