

Clinical parameters and biomarkers in blood and urine as predictors for bacteremia, hospital admission, morbidity and outcome in patients with complicated urinary tract infections. A study in primary care, the medicine emergency room and ICunit.

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Establish relevance of a clinical scoring system, and of established and to be identified biomarkers in blood and urine for clinical course and clinical and microbiological outcome of patients with a complicated urinary tract infection, treated in...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bacterial infectious disorders
Study type	Observational invasive

Summary

ID

NL-OMON30099

Source

ToetsingOnline

Brief title

Predictive value of biomarkers in complicated urinary tract infection.

Condition

- Bacterial infectious disorders
- Urinary tract signs and symptoms

Synonym

infection of kidney, Pyelonephritis

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Biomarkers, General practice, Sepsis, Urinary tract infection

Outcome measures

Primary outcome

Clinical cure (resolution of symptoms; determined by diary and follow up after one and three months) and microbiological cure (negative urine culture) after one month. Duration of fever, hospital and/or ICU stay, and outcome, both with respect to course of disease (fever days, development of circulatory shock, multiple organ dysfunction, need of stay in ICU stay and/or urological intervention, number of sick days) as well as recovery or death.

Secondary outcome

Course of microbiological and host-derived biomarkers in urine and serum, assessed by massspectrometry.

Study description

Background summary

For patients with pneumonia the risk of complications contributing to an adverse outcome, i.e., death, can be reliably estimated by means of a set of clinical criteria. If the risk estimator is small a patient may be treated at home with oral antibiotics, if the risk estimator is high hospital admission is advised. For complicated urinary tract infections a set of clinical criteria

have not been established.

Study objective

Establish relevance of a clinical scoring system, and of established and to be identified biomarkers in blood and urine for clinical course and clinical and microbiological outcome of patients with a complicated urinary tract infection, treated in primary care by their general practitioner, admitted to hospital and/or transferred to ICunit.

Study design

A prospective, observational, non-interventional multi-center cohort study.

Study burden and risks

Patients receive standard treatment for urinary tract infection, as put forward by the Dutch GP association 2005.

The burden of study procedures is minimal.

Blood is taken on day 0 and day 3 in patients enrolled by GPs.

In hospitalized patients, this blood sampling is combined with standard venapunctures, precluding additional procedures.

The risk of the study is minimal, the venapunctures will be conducted by qualified personnel.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- at least one symptom suggestive of urinary tract infection , and
- fever, and
- positive urine nitrate test or
- positive leukocyte esterase test

Exclusion criteria

- polycystic kidney disease
- end-stage renal failure
- renal transplant

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL
Recruitment status: Recruitment stopped
Start date (anticipated): 11-09-2006
Enrollment: 600
Type: Actual

Ethics review

Approved WMO
Application type: First submission
Review commission: METC Leiden-Den Haag-Delft (Leiden)
metc-ldd@lumc.nl

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
CCMO	NL11811.058.06