

Structured evaluation of adrenal gland tumors found incidentally during imaging studies.

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We hypothesize that urinary steroid profiling is cost-effective compared to repeat CT-scanning in patients with adrenal incidentalomas.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON22990

Bron

NTR

Verkorte titel

SERENDIPITY

Aandoening

adrenal incidentaloma
adrenocortical carcinoma
urinary steroid profiling

Ondersteuning

Primaire sponsor: University Medical Center Groningen
Amsterdam Medical Center

Overige ondersteuning: ZonMw

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome parameter is the difference in cost-effectiveness of the current management strategy based on repeat CT-scanning to detect adrenocortical carcinoma among patients with an adrenal incidentaloma compared with a strategy using a single baseline urinary steroid profiling.

Toelichting onderzoek

Achtergrond van het onderzoek

The standard diagnostic work-up for adrenal incidentaloma (AI) consists of biochemical analysis to detect hormonal hypersecretion and repeat CT-scanning as the primary diagnostic tool to demonstrate the presence of an adrenocortical carcinoma (ACC). However, prospective data describing the diagnostic yield and cost-effectiveness of repeat CT-scanning are limited. SERENDIPITY represents the largest prospective study on AI management thus far and aims to improve the cost-effectiveness of the diagnostic strategy by the application of a single baseline urinary steroid profiling (USP). In retrospective studies, it has been shown that USP distinguishes benign AI from ACC with high sensitivity and high specificity. If these promising results are to be confirmed in our study, then USP would offer a safe, patient-friendly and inexpensive alternative to repeat CT-scanning. In addition, we aim to examine the psychological impact for patients with AI being currently subjected to repeated laboratory tests and CT-scanning during several years.

Doel van het onderzoek

We hypothesize that urinary steroid profiling is cost-effective compared to repeat CT-scanning in patients with adrenal incidentalomas.

Onderzoeksopzet

- December 2014 – June, 2016: patient recruitment.
- December, 2014 – June, 2018: patient evaluation according to study algorithm, data collection and data entry.
- June, 2018 – December, 2018: data analysis and reporting.

Onderzoeksproduct en/of interventie

Not applicable.

This is not an interventional study per se, as patients with an adrenal incidentaloma are evaluated according to current management guidelines.

The diagnostic value of urinary steroid profiling will be assessed at the end of the study. Thus, the results of urinary steroid profiling will not affect the clinical management of participants with adrenal incidentaloma.

Contactpersonen

Publiek

Department of Endocrinology

University Medical Center Groningen
M.N. Kerstens
Groningen
The Netherlands
+31 (0)50 3616161/3518

Wetenschappelijk

Department of Endocrinology

University Medical Center Groningen
M.N. Kerstens
Groningen
The Netherlands
+31 (0)50 3616161/3518

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- adrenal mass > 1 cm in diameter incidentally discovered during CT-scanning, performed for reasons other than an evaluation for adrenal disease

- age 18 years or older

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- extra-adrenal malignancy (i.e. active or past medical history of malignancy, except for basal cell carcinoma)
- radiologic diagnosis of simple cyst or bilateral adrenal masses
- allergy to radiocontrast
- renal insufficiency (i.e. eGFR <30 /min/1.73m²)
- pregnancy
- inability to understand written Dutch

Onderzoeksopzet

Opzet

Type: Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel: Anders
Controle: N.v.t. / onbekend

Deelname

Nederland
Status: Werving nog niet gestart
(Verwachte) startdatum: 26-12-2014
Aantal proefpersonen: 1000
Type: Verwachte startdatum

Ethische beoordeling

Positief advies
Datum: 21-09-2014

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	NL4656
NTR-old	NTR4799
Ander register	837002503 : ZonMw project number

Resultaten