

# Kunnen kinderen (niet) goed beslissen over meedoen aan medicatieonderzoek?

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Once an objective test of competence becomes available for research practice, non-competent children will no longer have to go through the full informed consent procedure. Competent children will be more actively engaged in that procedure, with...

<b>Ethische beoordeling</b>	Niet van toepassing
<b>Status</b>	Werving gestart
<b>Type aandoening</b>	-
<b>Onderzoekstype</b>	Observationeel onderzoek, zonder invasieve metingen

## Samenvatting

### ID

NL-OMON27426

### Bron

NTR

### Verkorte titel

MacKID

### Aandoening

children's competence to consent, informed consent in minors, children's consent in drug trials.

wilsbekwaamheid bij kinderen, informed consent bij minderjarigen, informed consent bij kinderen in medicatieonderzoek.

## Ondersteuning

**Primaire sponsor:** Academic Medical Center Amsterdam and de Bascule Amsterdam

**Overige ondersteuning:** ZonMW

## Onderzoeksproduct en/of interventie

## Uitkomstmaten

### Primaire uitkomstmaten

1. MacCAT-CR scores and binary judgment of children's competence to consent;<br>
2. Reference standard of children's competence to consent;<br>
3. Validity and reliability of MacCAT-CR.

## Toelichting onderzoek

### Achtergrond van het onderzoek

Currently over 50% of drugs prescribed to children have not been studied in their age group. Prescribers often have no alternative but to choose off-label or unauthorised products. One key reason why children have historically been excluded from drug trials is that they are considered immature and not really capable of understanding research information. This conflicts with evidence that children as young as 9 years of age are capable of understanding the issues involved. If, however, we knew which children are capable of making well considered decisions about drug trial participation, it would be possible to involve children in a conforming way. More research on drugs in children would help all diseased children worldwide. An objective assessment of children's competence to consent is, however, currently not possible.

We propose to develop an instrument to assess children's competence to consent to research.

In this study we address the following research questions:

- 1) Can children's competence to consent be assessed in a reliable and valid way by means of a tool?
- 2) To what extent do age, IQ and contextual factors correlate with competence to consent?

### Doel van het onderzoek

Once an objective test of competence becomes available for research practice, non-competent children will no longer have to go through the full informed consent procedure. Competent children will be more actively engaged in that procedure, with extra weight given to their opinions. As this would do justice to the ethical principle of children as moral agents, it would have important intrinsic value.

### Onderzoeksopzet

After the usual informed consent procedure, within short notice the interview will be performed.

## Onderzoeksproduct en/of interventie

1. Videotaping of the usual informed consent procedure;
2. Modified MacCAT-CR semistructured interview;
3. Wechsler Nonverbal IQ subtests.

## Contactpersonen

### Publiek

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### Wetenschappelijk

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## Deelname eisen

### Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Age 6-18 years;
2. In informed consent procedure of medical research.

### Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Not speaking dutch.

## Onderzoeksopzet

### Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

### Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-01-2012
Aantal proefpersonen:	160
Type:	Verwachte startdatum

## Ethische beoordeling

Niet van toepassing	
Soort:	Niet van toepassing

## 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

<b>Register</b>	<b>ID</b>
NTR-new	NL3754
NTR-old	NTR3918
Ander register	ZonMW : 113105006
ISRCTN	ISRCTN wordt niet meer aangevraagd.

## Resultaten

### Samenvatting resultaten

<http://www.biomedcentral.com/1471-2431/12/156>