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

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON27426

Source
NTR

Brief title
MacKID

Health condition

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.

Sponsors and support

Primary sponsor: Academic Medical Center Amsterdam and de Bascule Amsterdam
Source(s) of monetary or material Support: ZonMW

Intervention

Outcome measures

Primary outcome

1. MacCAT-CR scores and binary judgment of children's competence to consent;

2. Reference standard of children's competence to consent;

3. Validity and reliability of MacCAT-CR.

Secondary outcome

Correlation of children's competence to consent to age, IQ, parental judgment of children's competence, ethnicity, trial- and illnessexperience.

Study description

Background summary

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?

Study objective

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.

Study design

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

Intervention

1. Videotaping of the usual informed consent procedure;

2. Modified MacCAT-CR semistructured interview;

3. Wechsler Nonverbal IQ subtests.

Contacts

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Eligibility criteria

Inclusion criteria

1. Age 6-18 years;

2. In informed consent procedure of medical research.

Exclusion criteria

Not speaking dutch.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2012
Enrollment:	160
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL3754
NTR-old	NTR3918
Other	ZonMW : 113105006
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
http://www.biomedcentral.com/1471-2431/12/156