

VAccination in ARThritis (VAART-onderzoek) - multicentre randomised clinical trial in patients with juvenile idiopathic arthritis: safety and efficacy of vaccination with live attenuated Measles, Mumps, Rubella vaccine

Submission date 23/08/2007	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 23/08/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 14/02/2019	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT00731965

Secondary identifying numbers

N/A

Study information

Scientific Title

VAccination in ARThritis (VAART-onderzoek) - multicentre randomised clinical trial in patients with juvenile idiopathic arthritis: safety and efficacy of vaccination with live attenuated Measles, Mumps, Rubella vaccine

Acronym

VAART

Study objectives

The primary objective of the study is to study the safety of Measles, Mumps, Rubella (MMR) booster vaccination in Juvenile Idiopathic Arthritis (JIA) patients by measuring JIA disease activity and the occurrence of measles, mumps or rubella infection.

The next primary objective is to evaluate the efficacy of the MMR booster vaccination in JIA patients by measuring protective immunity responses (specific anti measles, rubella, mumps antibodies by Enzyme-Linked Immunosorbent Assay [ELISA]) and functional antibody assays (measles neutralising antibodies) before and after MMR vaccination.

The secondary aim of the vaccination study is to analyse the influence on immune regulatory mechanisms capable of inducing JIA disease remission.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Centrale Commissie Mensgebonden Onderzoek (CCMO) and the Medical Ethics Committee of the participating centres for local feasibility, 07/02/2008, ref: NL 17376.000.07

Study design

Multi-centre prospective randomised controlled open-label vaccination study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Juvenile Idiopathic Arthritis (JIA)

Interventions

Included patients will be randomised for one extra MMR booster vaccination (at age 4 to 8) or no additional vaccination (controls). Placebo vaccines will not be used in the control group.

N.B. In the Netherlands all children receive MMR booster vaccination at 9 years of age. Patients in both groups will also receive their usual MMR booster vaccine at age 9 according to the National Vaccination Program.

Intervention Type

Biological/Vaccine

Primary outcome measure

Safety of MMR vaccination, according to:

1. JIA disease activity (defined by internationally validated core set criteria, number of disease flares in the 12 months after MMR vaccination and medication use), measured at baseline, and 3, 6 and 12 months after vaccination
2. Efficacy of MMR booster, defined by specific antibodies against measles, mumps and rubella, measured at baseline and 3 and 12 months after vaccination

Secondary outcome measures

Secondary outcome measures are:

1. Number of Tregs, that are capable to suppress proliferation in vitro
2. Presence of anti-inflammatory cytokine profiles following MMR booster
3. Number and function of MMR-specific T cells

These are measured at baseline and three months after vaccination.

Overall study start date

15/05/2008

Completion date

15/05/2011

Eligibility

Key inclusion criteria

1. All subtypes of JIA according to International League of Associations for Rheumatology (ILAR) criteria
2. Ages 4 to 8

Participant type(s)

Patient

Age group

Child

Lower age limit

4 Years

Upper age limit

8 Years

Sex

Both

Target number of participants

280

Key exclusion criteria

1. Use of Infliximab (Remicade, anti-Tumour Necrotising Factor [anti-TNF] alpha therapy)
2. Participation in another (drug) trial
3. Primary immunodeficiency
4. Fever less than 48 hour prior to vaccination (here the moment of vaccination will be postponed for one month)
5. Evidence of viral or bacterial infection less than 48 hours prior to vaccination (here the moment of vaccination will be postponed for one month)
6. Methylprednisolone pulse therapy less than one month prior to vaccination (in these cases, the moment of vaccination will be postponed for one month)

Please note that, as of 11/09/2008, the following exclusion criterion has been removed:
Use of Anakinra (Kineret, human interleukine-1-receptor antagonist)

Date of first enrolment

15/05/2008

Date of final enrolment

15/05/2011

Locations**Countries of recruitment**

Netherlands

Study participating centre

University Medical Centre Utrecht

Utrecht

Netherlands

3584 EA

Sponsor information

Organisation

University Medical Centre Utrecht (UMCU) (Netherlands)

Sponsor details

Wilhelmina Children's Hospital (WKZ)

PO Box 85090

KC.03.063.0

Utrecht

Netherlands

3508 AB

Sponsor type

Hospital/treatment centre

Website

<http://www.umcutrecht.nl/zorg/>

ROR

<https://ror.org/04pp8hn57>

Funder(s)**Funder type**

Hospital/treatment centre

Funder Name

University Medical Centre Utrecht (UMCU) (Netherlands)

Results and Publications**Publication and dissemination plan**

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
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[Results article](#)

results

19/06/2013

14/02/2019

Yes

No