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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

Registration date
23/08/2007

Last Edited
14/02/2019

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00731965

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

Primary study design
Interventional

Study design
Multi-centre prospective randomised controlled open-label vaccination study

Study type(s)
Prevention

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(s)
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

Key secondary outcome(s)
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.

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

Healthy volunteers allowed
No

Age group
Child

Lower age limit
4 Years

Upper age limit
8 Years

Sex
All

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)

ROR
https://ror.org/04pp8hn57

Funder(s)

Funder type
Hospital/treatment centre

Funder Name

University Medical Centre Utrecht (UMCU) (Netherlands)

Results and Publications

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?
Results article	results	19/06/2013	14/02/2019	Yes	No