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Treatment Interruption in Children with Chronic Human immunodeficiency virus infection: the TICCH Trial

Submission date	Recruitment status	[X] Prospectively registered
09/01/2004	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
25/02/2004	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
06/09/2021	Infections and Infestations	

Plain English summary of protocol
http://www.ctu.mrc.ac.uk/research_areas/study_details.aspx?s=25

Contact information

Type(s)
Scientific

Contact name
Dr Carlo Giaquinto

Contact details
Dipartimento di Pediatria
Universita di Padova
Via Giustiniani 3
Padova
Italy
35128
+39 (0)49 821 3563
carlog@pediatria.unipd.it

Additional identifiers

Protocol serial number
PENTA 11

Study information

Scientific Title

Treatment Interruption in Children with Chronic Human immunodeficiency virus infection: the TICCH Trial

Acronym
TICCH

Study objectives
The overall aim of the PENTA 11 trial is to evaluate the role of planned treatment interruptions in the management of Human Immunodeficiency Virus (HIV) infected children who have responded well to Anti-Retroviral Therapy (ART).

The specific objectives are:
1. To determine whether children with chronic HIV infection undergoing planned ART treatment interruptions are disadvantaged clinically, immunologically or virologically by periods of time off ART.
2. To assess HIV-specific immune responses during and after interruptions of ART, compared with continuous ART, in an immunology/virology substudy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Added as of 24/09/2007: Favourable ethics approval by Trent Multi-Centre Research Ethics Committee on 14/06/2004.

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Paediatric Human Immunodeficiency Virus (HIV)

Interventions
Status of trial as of 24/09/2007: Closed to recruitment. In follow-up.

Randomised controlled trial of planned treatment interruptions in children who are taking antiretoviral therapy for HIV infection. Randomised to one of two arms: continue therapy or CD4 driven planned treatment interruptions.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)

Anti-Retroviral Therapy (ART)

Primary outcome(s)
Primary outcome measures amended as of 24/09/2007:
CD4% less than 15% and/or new Centers for Disease Control and Prevention (CDC) stage C diagnosis:
1. CD4% less than 15% (age 2-6 years)
2. CD4% less than 15% and CD4 <200 cells/mm3 (age >7 years)
3. New CDC stage C diagnosis
4. Death

Primary outcome measures provided at time of registration:
CD4% less than 15% and/or new CDC (Centers for Disease Control and Prevention) stage C diagnosis.

Key secondary outcome(s))
1. Change in ART (defined as any change from the ART regimen at randomisation)
2. Acute retroviral syndrome
3. ART-related grade three and four clinical and laboratory adverse events
4. HIV-1 RNA equals 400 copies/ml at week 72 having received ART continuously for the preceding 12 weeks
5. HIV-1 RNA equals 50 copies/ml at week 72 having received ART continuously for the preceding 12 weeks
6. Number of HIV mutations present at 72 weeks conferring resistance to drugs taken at entry or during the trial
7. Adherence to ART as assessed by caregiver completed questionnaire
8. Acceptability of the two strategies of ART administration to paediatricians and families

Completion date
18/06/2008

Eligibility

Key inclusion criteria
Inclusion criteria amended as of 24/09/2007:
1. Aged 2 to 15 years inclusive
2. Parents/guardians, and children where appropriate, willing and able to give informed consent
3. Children currently on the same regimen of three or more antiretroviral (ART) drugs for at least 24 weeks
4. Children and parents prepared to restart the same ART regimen after treatment interruption if CD4% falls to <20% (children aged 2-6 years) or CD4% falls to <20% or CD4 count falls to <350 cells/mm3 (children aged >7 years) (confirmed on a second sample) or after 48 weeks on a PTI
5. Most recent two plasma HIV-1 Ribonucleic Acid (RNA) viral load less than 50 copies/ml (at least one month apart)
6. Most recent two CD4% >30% (children aged 2-6 years) or most recent two CD4% >25% and CD4 count >500 cells/mm3 (children aged >7 years); most recent two CD4% should be stable (different by no more than 4%)
7. Most recent two Total Lymphocyte Count (TLC) more than 1000 (at least one month apart)
8. Willing to attend 4 weekly monitoring visits if CD4 declines to <400 cells/mm3 or CD4% <22%

Inclusion criteria provided at time of registration:
1. Aged 2 to 15 years inclusive
2. Parents/guardians, and children where appropriate, willing and able to give informed consent
3. Children currently on the same regimen of three or more antiretroviral (ART) drugs for at least 24 weeks
4. Children and parents prepared to restart the same ART regimen after treatment interruption if CD4% falls below 20% (aged two to six years) or CD4% falls to less than 20% and CD4 count falls to less than 350 cells/mm^3 (confirmed on a second sample). Children and parents prepared to continue on current therapy until clinical or virological failure if randomised to the continuous therapy arm
5. Most recent two plasma HIV-1 Ribonucleic Acid (RNA) viral load less than 50 copies/ml (at least one month apart)
6. Most recent two CD4% equal 30% (children aged two to six years) or most recent two CD4% equals 25% and CD4 count is more than 350 cells/mm^3. Most recent two CD4% should be stable (different by no more than 4%)
7. Most recent two Total Lymphocyte Count (TLC) more than 1000 (at least one month apart)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
2 years

Upper age limit
15 years

Sex
All

Key exclusion criteria
Exclusion criteria amended as of 24/09/2007:
1. Cannot or unwilling to attend regularly
2. Unwilling to restart ART if CD4 percent or count indicates this is necessary
3. Intercurrent illness (randomisation can take place after the illness)
4. Pregnancy or risk of pregnancy in girls of child-bearing potential
5. Previous symptomatic thrombocytopaenia with platelets <50 x 10 (to the power of 9)/l
6. Positive for hepatitis B surface antigen and receiving either lamivudine or tenofavir

Exclusion criteria provided at time of registration:
1. Cannot or unwilling to attend regularly
2. Unwilling to restart ART if CD4 percent or count indicates this is necessary
3. Intercurrent illness (randomisation can take place after the illness)
4. Pregnancy or risk of pregnancy in girls of child-bearing potential

Date of first enrolment
01/11/2004

Date of final enrolment
18/06/2008

Locations

Countries of recruitment
United Kingdom

France

Germany

Ireland

Italy

Spain

Switzerland

Thailand

United States of America

Study participating centre
Dipartimento di Pediatria
Padova
Italy
35128

Sponsor information

Organisation
The Paediatric European Network for the Treatment of AIDS (PENTA) Foundation (Italy)

ROR
https://ror.org/03ash3475

Funder(s)

Funder type

Government

Funder Name
European Union funding (ref: QLK2-2000-00150)

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	15/05/2008		Yes	No
Results article	results	16/01/2010		Yes	No
Results article	results	20/02/2013		Yes	No
Results article	Follow up study	29/07/2021	06/09/2021	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes