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Type 1 diabetes monitoring and ophthalmic complications in children in the Democratic Républic of Congo

Submission date
18/04/2024

Recruitment status
No longer recruiting

Registration date
16/05/2024

Overall study status
Ongoing

Last Edited
16/05/2024

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
In the Democratic Republic of Congo (DRC), it's common for children with Type 1 diabetes to develop a condition called diabetic retinopathy (DR), which affects the eyes. However, we've found that by educating patients about managing their condition and using continuous glucose monitoring systems (CGM) that measure glucose levels under the skin, we can decrease the occurrence of DR in these children in the DRC.

Who can participate?
This study includes children with Type 1 diabetes, with or without DR, from different diabetes clinics in Kinshasa managed by the Diocesan Medical Works Office (BDOM).

What does the study involve?
This research compares various aspects of health, including biological markers, eye health, and overall physical well-being, as well as the effectiveness of managing Type 1 diabetes and the advancement of diabetic retinopathy (DR) in two groups of children. One group uses a continuous glucose monitoring system (CGM), specifically the Dexcom one, while the other group monitors their blood glucose levels through self-testing.

What are the possible benefits and risks of participating?
During the study, all necessary monitoring equipment will be provided. They also get free medical tests and eye check-ups. They will receive guidance on managing their condition through patient therapeutic education.

Where is the study run from?
University Clinic of Kinshasa (Democratic Republic of Congo)

When is the study starting and how long is it expected to run for?
October 2023 to December 2025

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Christophe NTALU, ntachristophe1@gmail.com

Contact information

Type(s)
Public, Scientific

Contact name
Prof Celestin NSIBU

Contact details
Pediatric Departement
University Clinic of Kinshasa
Faculté de Médecine de Kinshasha
Kinshasa
Congo, Democratic Republic
-
+243 999 923 676
celensibu@gmail.com

Type(s)
Scientific

Contact name
Prof Moïse MVITU

Contact details
Opthalmology Service
University Clinic of Kinshasa
kinshasa
Congo, Democratic Republic
-
+243 815 107 626
moisemvitu2001@gmail.com

Type(s)
Scientific

Contact name
Prof Jean Robert MAKULO RISSASSI

Contact details
Medecine Departement
University Clinic of Kinshasa
kinshasa
Congo, Democratic Republic

-
+243990 205 367
jrmakulo2016@gmail.com

Type(s)
Scientific

Contact name
Prof Marie claire MUYER

Contact details
University Clinic of Kinshasa
Kinshasa
Congo, Democratic Republic
-
+243 811 452 711
muel-telo@yahoo.fr

Type(s)
Scientific

Contact name
Prof Georges MVUMBI LELO

Contact details
University of Kinshasa
Faculty of Medecine
kinshasa
Congo, Democratic Republic
-
-
mvumbilelo@yahoo.fr

Type(s)
Principal Investigator

Contact name
Dr Christophe NTALU

ORCID ID
http://orcid.org/0009-0005-3925-9559

Contact details
Pediatric Department
University Clinic of Kinshasa
kinshasa
Congo, Democratic Republic
-
+33 6 85 36 80 63
christophe.ntalu@ch-stdenis.fr

Type(s)
Scientific

Contact name
Prof Adolphine NKUADIOLANDU

Contact details
Pediatric Department
University Clinic of Kinshasa
Kinshasa
Congo, Democratic Republic
-
+243 844 297 614
nkuadiolandu@gmail.com

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
STUDY DT1/RD3

Study information

Scientific Title
Type 1 diabetes in children and diabetic retinopathy in the Congolese environment: clinical, therapeutic and preventive approach

Study objectives
The use of continuous glucose monitoring (CGM) sensors can improve diabetes management and the progression of microangiopathic complications (diabetic retinopathy) in children with type 1 diabetes in the city of Kinshasa in the Democratic Republic of the Congo

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 25/10/2023, National Health Ethics comimittee of Democratic Republic of Congo (PNMLS Building, local 5 Kasa vubu, Kinshasa, -, Congo, Democratic Republic; +243 99 84 19 816; feli1munday@yahoo.fr), ref: 490/CNES/BN/PMMF/2023

Study design
Multicenter interventional randomized control trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Care home, Hospital, Laboratory, University/medical school/dental school

Study type(s)
Diagnostic, Prevention, Treatment, Efficacy

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Type 1 diabetes, diabetic retinopathy

Interventions
We sampled type 1 diabetic patients aged 5 to 18 years with early-stage diabetic retinopathy. After 1:3 randomization, two groups were formed: group 1 used continuous glucose monitoring (CGM) with Dexcom one sensor for glycemic control, measuring interstitial glucose, while group 2 utilized fingerstick glycemic control, measuring capillary glucose. Biological parameters (HbA1c and microalbuminuria) were followed up at months 1, 3, 6, 9, and 12, and diabetic retinopathy stage was assessed at months 1 and 12.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Dexcom ONE sensor

Primary outcome measure
1. Hb1Ac levels measured using the Siemens DCA VANTAGE analyzer at months 1, 3, 6, 9, and 12
2. Microalbuminuria measured using the Siemens DCA VANTAGE analyzer at months 1, 3, 6, 9, and 12
3. Stages of diabetic retinopathy measured using the 2016 standards for screening and surveillance of ocular complications in people with diabetes at months 1 and 12

Secondary outcome measures
1. Glycemic average measured using the following standard formula: Hb1ac (in %) x 1.59 - 2.59 at months 1, 3, 6, 9, and 12

2. Time in range (TIR) measured using a Dexcom ONE MCG sensor at months 1, 3, 6, 9, and 12
3. Body mass index (BMI) calculated by dividing weight in kg by height in cm squared at months 1, 3, 6, 9, and 12

Overall study start date
25/10/2023

Completion date
31/12/2025

Eligibility

Key inclusion criteria
1. Children under 18 years of age, of both sexes, followed in the six diabetic clinics in Kinshasa
2. Known diabetic with diabetic retinopathy
3. No-sickle cell children
4. Informed consent from parents

Participant type(s)
Patient

Age group
Child

Lower age limit
5 Years

Upper age limit
18 Years

Sex
Both

Target number of participants
1000

Key exclusion criteria
1. Age over 18 years
2. Non-type1 diabetes millitus
3. Non-consent

Date of first enrolment
04/03/2024

Date of final enrolment
30/12/2024

Locations

Countries of recruitment

Congo, Democratic Republic

Study participating centre
The six diabetic clinics of the city of Kinshasa (RDC)
Kinshasa
Congo, Democratic Republic
-

Sponsor information

Organisation
University Clinic of Kinshasa

Sponsor details
Pediatric Department
Kinshasa
Congo, Democratic Republic
-
+ 243 844 297 614
nkuadiolandu@gmail.com

Sponsor type
University/education

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
30/12/2025

Individual participant data (IPD) sharing plan

Data sharing plans for the ongoing study are currently unknown and will be available at later date

IPD sharing plan summary

Data sharing statement to be made available at a later date