

# DATURA

Determination of Adequate **TU**berculosis Regimen in Adults and adolescents hospitalised with HIV-associated severe immune suppression (NCT04738812)



The DATURA project is funded by the EDCTP2 programme (Grant RIA2018-CO-2515) supported by the European Union and Inserm-ANRS. Inserm-ANRS is the sponsor of the research (ANRS 12424 DATURA) and the funder of the Asian component.

## Remind about DATURA

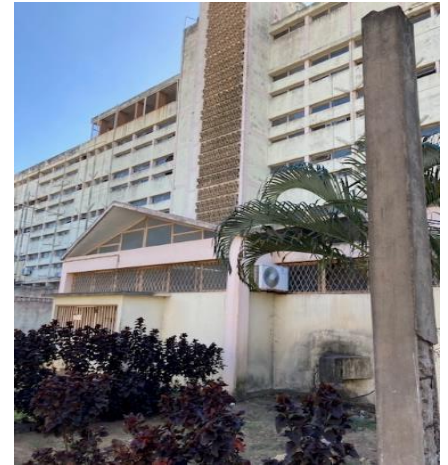
DATURA is a clinical trial assessing whether an intensified initial TB treatment increases survival in hospitalised, HIV-infected adults and adolescents in sub-Saharan Africa and South-East Asia. 1,330 participants are expected to be enrolled.

DATURA is registered in ClinicalTrials.gov: [NCT04738812](https://clinicaltrials.gov/ct2/show/study/NCT04738812)

## Check out our website

<https://datura.w.uib.no>

### Machava TB referral Hospital in Maputo, Mozambique



## Trial progress

After a long phase of preparation and authorisation approvals, Guinea (Conakry) was the first site to **start recruitment in April 21, 2022**, followed by the Cambodia site (Phnom Penh) in May 20, 2022, the Zambia site (Lusaka) in August 8, 2022, the Cameroon site (Yaoundé) in August 8, 2022 and the Uganda site (Mbarara) in August 19, 2022. A second site (Douala) opened in Cameroon and started inclusions on September 30, 2023. Unfortunately, the Vietnam (Ho Chi Minh city) site could not open for administrative issues and was replaced by Mozambique (Maputo) that started inclusions on February 15, 2024.

### Centre for Respiratory Diseases of Laquintinie Hospital in Douala, Cameroon



From the outset of inclusion, all countries except Guinea experienced recruitment difficulties. Some obstacles were identified, such as the drop in post-COVID-19 hospital admissions, some overly restrictive eligibility criteria, or a significant number of pre-included people with CD4 counts above 100 cells/ $\mu$ L. Moreover, inclusions had to be stopped for 3 months in Zambia (administrative issues) and the study team was modified as follows: Dr Suilanji SIVILE and Prof. Lloyd MULENGA are the new principal investigator and co-investigator, respectively.

## DATURA Newsletter 2024-1

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### Trial progress (to be continued)

By the end of April 2024, **627 participants had been randomised.**

The first participants were enrolled at a very advanced clinical stage (median BMI of 17.6, including 30% with a BMI<16; median haemoglobin rate of 9 g/dL; median CD4 of 41 cells/ $\mu$ L). Most of them (72%) discovered their HIV status at the time of inclusion. Nearly 70% of participants were enrolled with a positive Xpert MTB/RIF<sup>®</sup> test, 25% with a positive urine LAM test and only 5% on the basis of a sole highly suggestive chest X-ray.

### Independent data and safety monitoring board (DSMB) review

Since the beginning of inclusions, the independent DSMB had 3 opportunities to review the trial progress (October 24, 2022; June 18, 2023; November 27, 2023) and saw no reason to consider stopping the trial.

### AFRAVIH 2024 – Yaoundé April 16-19, 2024

**Prof. Charles KOUANFACK**, co-principal investigator of DATURA in Cameroon, chaired the XII<sup>th</sup> AFRAVIH conference. Together with the Cameroon team, several members of DATURA attended the conference: Dr Boubacar Djelo DIALLO, the principal investigator of Guinea, Dr Maryline BONNET, the leader of Work Package 5, Dr Didier LAUREILLARD and Prof. F.Xavier BLANC, the coordinating investigators.



During an oral communication session, **Dr Lauriane FOMETE** (DATURA project manager in Cameroon) presented the baseline characteristics of the first 577 DATURA participants.



### Next steps

**Joint Project Steering Committee and Data and Safety Monitoring Committee meeting: July 8-9, 2024.**

Inclusions will continue until December 2024.

The end of the trial is expected on December 2025.

The results are expected by mid-2026.

### To be noted...

DATURA trial is cited in "The advanced HIV disease research landscape" WHO report published on February 19, 2024. <https://www.who.int/publications/i/item/9789240089020>

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