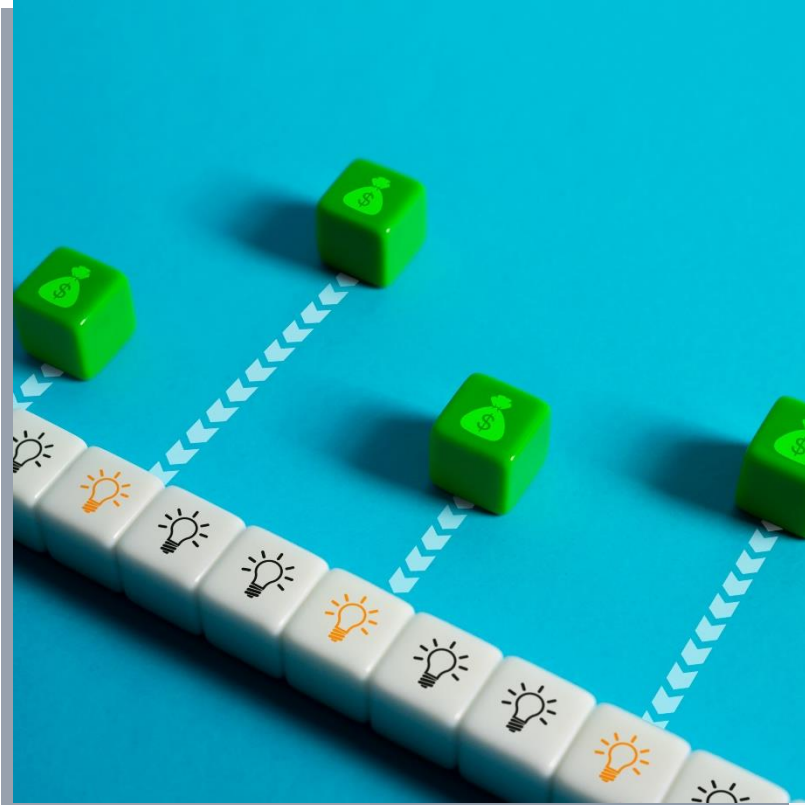


2025 investigator-led call: information session

Welcome & Agenda



Agenda Information Session KCE Trials Call 2025 - 5th June 2025

Subject	Presenter (all KCE)	Time
Please connect to meeting 5 min in advance		
Welcome	France Vrijens <i>Head of KCE Trials</i>	10 min
What is the scope of the KCE Trials Programme? Which trials do we fund? Criteria of the 2025 investigator-led call	Frank Hulstaert <i>Senior Researcher</i>	15 min
What are pragmatic Trials? What are patient-centred outcomes?	Leen Verleye <i>KCE expert physician</i>	25 min
Practical information on submission and selection procedure	Lisa Marynen <i>Call coordinator</i>	20 min
Q&A session	<i>All</i>	50 min



Practicalities



- No recording
- Please mute yourself
- Slides available next week (in your mail)



Questions ?

- No content question in chat
- On content ? 5 min after each session
- On individual projects ? at the end
- Please raise your virtual hand and say who you are
- No time or not willing to share your question? Please first contact your CTC (and then us)



Who is attending?

- Almost all academic hospitals & universities
- Non academic hospitals
- Clinical Trials Centers (CTCs)
- Public Research Institute
- Other

CHU Liege

ITG

Jan Yperman

Jessa ZH

KU Leuven

Other

Sciensano

U Gent

U Hasselt

UCL

UZ Brussel

UZ Gent

UZ Leuven

UZA

VUB

ZAS



KCE TRIALS IN A NUTSHELL 2024

Specificities

- ✓ Pragmatic & practice oriented
- ✓ Comparative effectiveness
(drugs, devices, surgery, physiotherapy, psychotherapy...)
- ✓ Drug repurposing
(off-patent drugs)
- ✓ Non-commercial
- ✓ Potential for return on investment
- ✓ Data sharing

Quality support

- Sponsor capacity assessed for all trials
- Trainings for Clinical Trials Centres
- Coaching of funded teams
- External audits of ongoing trials

Calls for research proposals

3 calls in 2024

9th national call

Endometriosis themed call

4th call

BeNeFIT
with ZonMw (NL)

24%

success rate
2021-2022



Investigator-led calls
Bottom up

Commissioned calls
Top down

+ Funding of Belgian participation to international studies

Funding budget

10 million €
annual budget

- Median budget per trial 2 million €
- Milestone-based budget
- Use of template to budget non-commercial research

Funded Trials

Ongoing

41

Completed

15

+ 30 000
participants recruited



Hospitals



Primary care



Check the realtime recruitment in our dynamic dashboards

Impact

75

scientific peer
reviewed
publications

HTA
& linkage with
Real World Data

Changes to
clinical
guidelines



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trials@kce.fgov.be



[LinkedIn Trials](#)



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Irritable bowel syndrome



Original research

Diet or medication in primary care patients with IBS: the DOMINO study - a randomised trial supported by the Belgian Health Care Knowledge Centre (KCE Trials Programme) and the Rome Foundation Research Institute

Florencia Carbone,^{1,2} Karen Van den Houte,² Linde Besard,¹ Céline Tack,¹ Joris Arts,^{1,3} Philip Caenepeel,^{1,3} Hubert Piessevaux,⁴ Alain Vandenberghe,⁵ Christophe Matthys,⁶ Jessica Biesiekierski,^{2,7} Luc Capiou,⁸ Steven Ceulemans,⁸ Olivier Gernay,⁸ Lydia Jones,⁸ Sophie Maes,⁸ Christian Peetermans,⁸ Willem Raat,⁹ Jeroen Stubbe,⁸ Rudy Van Boxtael,⁸ Olivia Vandeput,⁸ Sophie Van Steenberghe,⁸ Lukas Van Oudenhove,² Tim Vanuytsel,^{1,2} Michael Jones,¹⁰ Jan Tack ,^{1,2,11,12} DOMINO Study Collaborators¹³



JAMA | Original Investigation | CARING FOR THE CRITICALLY ILL PATIENT

Continuous vs Intermittent β -Lactam Antibiotic Infusions in Critically Ill Patients With Sepsis The BLING III Randomized Clinical Trial

Joel M. Dulhunty, MD, PhD; Stephen J. Brett, MD; Jan J. De Waele, MD, PhD;
Dorilyn Rajbhandari, PGDip(Clinical Nursing); Laurent Billot, MRes; Menino O. Cotta, PhD;
Joshua S. Davis, MD, PhD; Simon Finfer, MD; Naomi E. Hammond, RN, PhD; Serena Knowles, RN, PhD;
Xiaoqiu Liu, PhD; Shay McGuinness, MD; Jayanthi Mysore, MS; David L. Paterson, MD, PhD;
Sandra Peake, MD, PhD; Andrew Rhodes, MD, MD(Res); Jason A. Roberts, BPharm, PhD; Claire Roger, MD, PhD;
Charudatt Shirwadkar, MD; Therese Starr, RN; Colman Taylor, PhD; John A. Myburgh, MD, PhD;
Jeffrey Lipman, MD, DMed(Res); for the BLING III Study Investigators

IMPORTANCE Whether β -lactam antibiotics administered by continuous compared with intermittent infusion reduces the risk of death in patients with sepsis is uncertain.

OBJECTIVE To evaluate whether continuous vs intermittent infusion of a β -lactam antibiotic (piperacillin-tazobactam or meropenem) results in decreased all-cause mortality at 90 days in critically ill patients with sepsis.

- [+ Visual Abstract](#)
- [+ Editorial](#)
- [+ Multimedia](#)
- [+ Related article](#)
- [+ Supplemental content](#)



Effect of high versus standard protein provision on functional recovery in people with critical illness (PRECISE): an investigator-initiated, double-blinded, multicentre, parallel-group, randomised controlled trial in Belgium and the Netherlands



Julia L M Bels, Steven Thiessen, Rob J J van Gassel, Albertus Beishuizen, Ashley De Bie Dekker, Vincent Fraipont, Stoffel Lamote, Didier Ledoux, Clarissa Scheeren, Elisabeth De Waele, Arthur R H van Zanten, Laura Bormans-Russell, Bas C T van Bussel, Marlies M J Dictus, Tom Fizez, Ingeborg Harks, Iwan C C van der Horst, Joop Jonckheer, Hugues Marechal, Paul B Massion, Ingrid Meex, Michelle C Paulus, Martin Rinket, Susanne van Santen, Katrien Tartaglia, Adam M Deane, Frieda Demuydt, Zudin Puthucheary, Lilian C M Vloet, Peter J M Weijs, Sander M J van Kuijk, Marcel C G van de Poll, Dieter Mesotten*, on behalf of the PRECISE study team†*

Summary

Background Increased protein provision might ameliorate muscle wasting and improve long-term outcomes in critically ill patients. The aim of the PRECISE trial was to assess whether higher enteral protein provision (ie, 2·0 g/kg per day) would improve health-related quality of life and functional outcomes in critically ill patients who were mechanically ventilated compared with standard enteral protein provision (ie, 1·3 g/kg per day).

Lancet 2024; 404: 659–69

See Comment page 630

*Joint senior authors and contributed equally



The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Acetazolamide in Acute Decompensated Heart Failure with Volume Overload

W. Mullens, J. Dauw, P. Martens, F.H. Verbrugge, P. Nijst, E. Meekers,
K. Tartaglia, F. Chenot, S. Moubayed, R. Dierckx, P. Blouard, P. Troisfontaines,
D. Derthoo, W. Smolders, L. Bruckers, W. Droogne, J.M. Ter Maaten,
K. Damman, J. Lassus, A. Mebazaa, G. Filippatos, F. Ruschitzka, and M. Dupont,
for the ADVOR Study Group*

ABSTRACT



Gonoscreen study - SPONSOR ITM



The Lancet HIV
Volume 11, Issue 4, April 2024, Pages e233-e244



Articles

Effect of screening for *Neisseria gonorrhoeae* and *Chlamydia trachomatis* on incidence of these infections in men who have sex with men and transgender women taking HIV pre-exposure prophylaxis (the Gonoscreen study): results from a randomised, multicentre, controlled trial

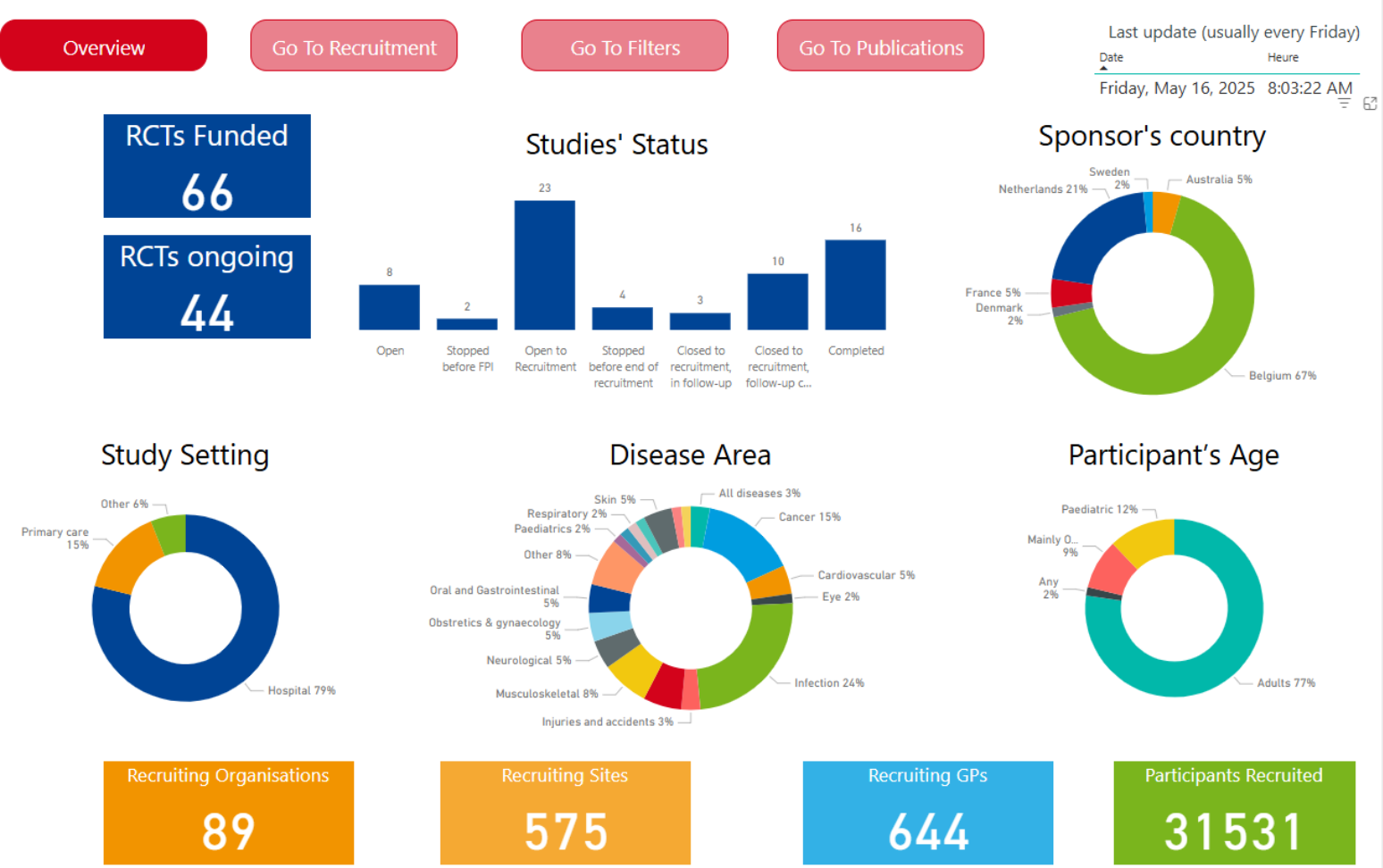
Thibaut Vanbaelen PhD ^a  , Achilleas Tsoumanis PhD ^a, Eric Florence PhD ^{a, c},
Christophe Van Dijck PhD ^a, Diana Huis in 't Veld PhD ^d, Anne-Sophie Sauvage MD ^f,
Natacha Herssens MSc ^a, Irith De Baetselier PhD ^a, Anke Rotsaert MSc ^b,
Prof Veronique Verhoeven PhD ^h, Sophie Henrard MD ⁱ, Yven Van Herrewege PhD ^a,
Dorien Van den Bossche PhD ^a, Prof Jean-Christophe Goffard PhD ⁱ, Elizaveta Padalko PhD ^e,
Thijs Reyniers PhD ^b, Bea Vuylsteke PhD ^b, Charlotte Michel MD ^k, Marie-Pierre Hayette PhD ^g,
Agnes Libois MD ^j [†], Prof Chris Kenyon PhD ^a [†]

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Dynamic dashboards

■ trials.kce.be/dashboard/

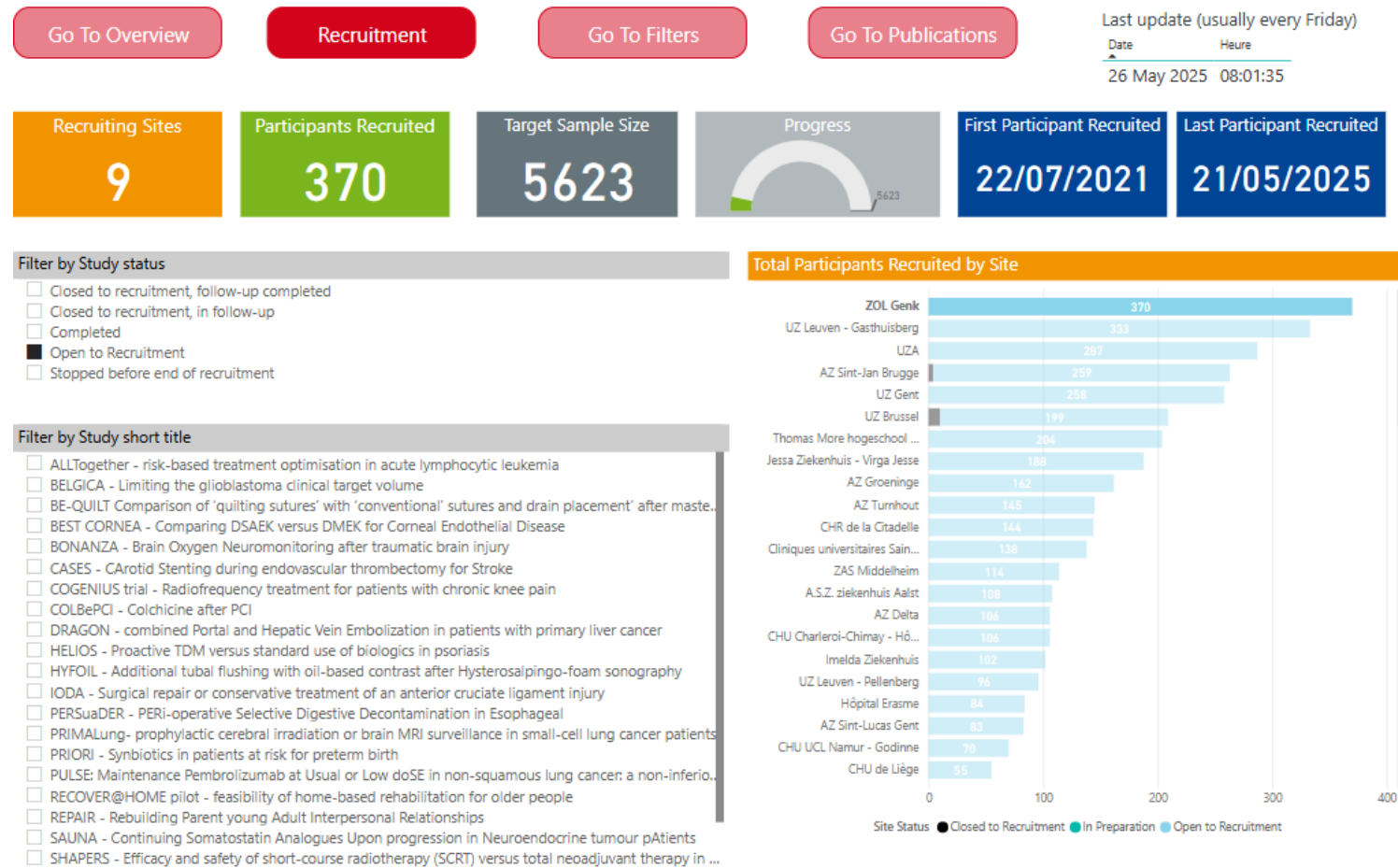


Dynamic dashboards

■ trials.kce.be/dashboard/



KCE Trials Dynamic Dashboard



Project Short Title	Recruiting Site	Site Status	PI Name	Number of patient randomized	Date first participant recruited	Date last participant recruited
BELGICA - Limiting the glioblastoma clinical target volume	ZOL Genk	In Preparation	Govers Mieke	0		
BE-QUILT Comparison of 'quilting sutures' with 'conventional' sutures and drain placement' after mastectomy	ZOL Genk	Open to Recruitment	Van de Putte Greg	1	15/01/2025	15/01/2025
BEST CORNEA - Comparing DSAEK versus DMEK for Corneal Endothelial Disease	ZOL Genk	Open to Recruitment	Gast Sacha	14	13/03/2023	31/05/2024
BONANZA - Brain Oxygen Neuromonitoring after traumatic brain injury	ZOL Genk	Open to Recruitment	Williaert Xavier	6	01/02/2025	19/05/2025
COGENIUS trial - Radiofrequency treatment for patients with chronic knee pain	ZOL Genk	Open to Recruitment	Van der Veken	14	07/03/2023	31/05/2024



Dynamic dashboards

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Filters

Go To Publications

Last update (usually every Friday)

Date

Heure

26 May 2025 08:01:35

Local project reference

Search

Project Short Title

Search

Local project reference	Project Short Title	Project status	Results	Chief Investigator/National Coordinator (BE)	Sponsors	KCE website
KCE-17002	AGNOHSTIC - Pregnancy after adhesion reducing gel after operative hysteroscopy	Closed to recruitment, follow-up completed	2025	Steven Weyers	UZ Gent - Universitair Ziekenhuis Gent	KCE website
KCE19-1224	HYFOIL - Additional tubal flushing with oil-based contrast after Hysterosalpingo-foam sonography	Open to Recruitment	2027	Diane De Neubourg	UZA - Universitair Ziekenhuis Antwerpen	KCE website
KCE20-1273	PRIORI - Synbiotics in patients at risk for preterm birth	Open to Recruitment	2026	Caroline Van Holsbeke	ZOL - Ziekenhuis Oost-Limburg	KCE website

Filter by Call for Proposals

☐ Select all

☐ 2017 Investigator-led call

☐ 2019 Investigator-led call

☐ 2020 Investigator-led call

Filter by Study Setting

☐ Select all

☐ Hospital

Filter by Study Status

☐ Select all

☐ Closed to recruitment, follow-up completed

☐ Open to Recruitment

Filter by Participant's Age

☐ Select all

☐ Adults

Filter by - Participants recruited in ICU ?

☐ Select all

☐ No

Filter by - Surgery Study ?

☐ Select all

☐ No

☐ Yes

Filter by - Medication Study ?

☐ Select all

☐ No

Filter by Disease Area

☒ Select all

☐ All diseases

☐ Cancer

☐ Cardiovascular

☐ Eye

☐ Infection

☐ Injuries and accidents

☐ Mental Health

☐ Musculoskeletal

☐ Neurological

☒ Obstetrics & gynaecology

☐ Oral and Gastrointestinal

Filter by Sponsor

Lead country, Sponsors

☐ Select all

☐ Belgium



Dynamic dashboards

■ trials.kce.be/dashboard/



KCE Trials Dynamic Dashboard

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[Go To Filters](#)
[Publications](#)

Last update (usually every Friday)
Date: 26 May 2025
Heure: 08:01:35

Filter on Study

- ☐ Select all
- ☐ ADVOR
- ☐ BeNeDuctus
- ☐ Big Bird
- ☐ BLING-III
- ☐ CareRa2020

Filter on Category of Publication

- ☐ guidelines
- ☐ Methods
- ☐ Protocol
- ☐ Qualitative
- ☒ Results
- ☐ SAP

Filter on Year of Publication

2016 2025

Peer Reviewed Publications
42

Year of publication	Category	ACRONYM	Title publication	Journal	Link to publication
2025	Results	C-EASIE	Early administration of vitamin C in patients with sepsis or septic shock in emergency departments: a multicenter, double-blind, randomized controlled trial: the C-EASIE trial	Critical Care	Link
2024	Results	BLING-III	Continuous vs Intermittent β -Lactam Antibiotic Infusions in Critically Ill Patients With Sepsis	JAMA	Link
2024	Results	PRECISE	The BLING III Randomized Clinical Trial	The Lancet	Link
2024	Results	GonoScreen	Effect of high versus standard protein provision on functional recovery in people with critical illness (PRECISE): an investigator-initiated, double-blinded, multicentre, parallel-group, randomised controlled trial in Belgium and the Netherlands	Lancet HIV	Link
2024	Results	CareRa2020	Effect of screening for <i>Neisseria gonorrhoeae</i> and <i>Chlamydia trachomatis</i> on incidence of these infections in men who have sex with men and transgender women taking HIV pre-exposure prophylaxis (the Gonoscreen study): results from a randomised, multicentre, controlled trial	RMD Open	Link
2024	Results	PuRe-COVID	Effectiveness of methotrexate and bridging glucocorticoids with or without early introduction of a 6-month course of etanercept in early RA: results of the 2-year, pragmatic, randomised CareRA2020 trial	ERJ Open Res	Link
2024	Results	IMCOVAS	Evaluation of the learning effect on the six-minute walk distance in adults with long COVID	Vaccine	Link
2024	Results	Prevention Pressure Ulcer	Humoral immune response against SARS-CoV-2 after adapted COVID-19 vaccine schedules in healthy adults: The IMCOVAS randomized clinical trial	Journal of Tissue Viability	Link
2024	Results	DUET	Silicone adhesive multilayer foam dressings to prevent hospital-acquired sacrum pressure ulcers: An economic evaluation based on a publicly funded pragmatic randomized controlled trial linked with real-world data	Clinical Infectious Diseases	Link
2024	Results	RESET-ASDH	Superiority trials in invasive aspergillosis: a harsh reality check with the IA-DUET (HOVON502) trial	Brain and Spine	Link
2023	Results	Big Bird	The death of a neurotrauma trial lessons learned from the prematurely halted randomized evaluation of surgery in elderly with traumatic acute subdural hematoma (RESET-ASDH) trial	Heliyon	Link
2023	Results	Foot Drop	"At the time I only wanted to relieve stress": Exploring motivation for behaviour change in long-term hypnotic users	Pilot and Feasibility Studies	Link
2023	Results	SAFEBOOSC III	A randomized controlled trial comparing conservative versus surgical treatment in patients with foot drop due to peroneal nerve entrapment: results of an internal feasibility pilot study	NEJM	Link
2023	Results	PELICAN	Cerebral Oximetry Monitoring in Extremely Preterm Infants	Pain Research and Management	Link
2023	Results	CONFIDENT	Considerations on the Obstacles That Lead to Slow Recruitment in a Pain Management Clinical Trial: Experiences from the Belgian PELICAN (Prégabalin Lidocaine Capsaicin Neuropathic Pain) Pragmatic Study	NEJM	Link
2023	Results	ADVOR	Convalescent Plasma for Covid-19-Induced ARDS in Mechanically Ventilated Patients	Circulation	Link
2023	Results	Big Bird	Decongestion With Acetazolamide in Acute Decompensated Heart Failure Across the Spectrum of Left Ventricular Ejection Fraction: A Prespecified Analysis From the ADVOR Trial	JMIR Formative Research	Link
2023	Results	ADVOR	Implementing Blended Care to Discontinue Benzodiazepine Receptor Agonist Use for Insomnia: Process Evaluation of a Pragmatic Cluster Randomized Controlled Trial	J Am Coll Cardiol.	Link
2023	Results	ADVOR	Natriuretic Response to Acetazolamide in Patients With Acute Heart Failure and Volume Overload.	Eur Heart J	Link
2023	Results	ADVOR	Pre-treatment bicarbonate levels and decongestion by acetazolamide: the ADVOR trial.	European Heart Journal	Link
2023	Results	ADVOR	Renal function and decongestion with acetazolamide in acute decompensated heart failure: the ADVOR trial	Eur J Heart Fail.	Link
2023	Results	DAWN Antivirals	Sodium and potassium changes during decongestion with acetazolamide – a pre-specified analysis from the ADVOR trial	BJGP Open	Link
2022	Results	ADVOR	The DAWN antivirals trial: process evaluation of a COVID-19 trial in general practice	NEJM	Link
2022	Results	ADVOR	Acetazolamide in Acute Decompensated Heart Failure with Volume Overload	Eur J Heart Fail.	Link
2022	Results	Big Bird	Acetazolamide in Decompensated Heart Failure with Volume Overload trial (ADVOR): baseline characteristics	Sleep	Link
2022	Results	Big Bird	Blended care to discontinue BZRA use in patients with chronic insomnia disorder: a pragmatic cluster randomized controlled trial in primary care		



How to receive the KCE Trials newsletter?

<https://kce.fgov.be/en/kce-trials>

Home > KCE Trials

KCE Trials

About KCE Trials

- What is the KCE Trials programme?
- Which tools does KCE Trials provide to support clinical research in our country?
- Does KCE Trials take into account the views of the patients?
- When and why was KCE Trials set up?
- What type of clinical trials does KCE Trials fund?
- Where and by whom are the clinical trials conducted?

Calls

- Future calls
- Open calls
- Closed calls
- What are calls for proposals?
- How are proposals selected?

News and upcoming events

- 2021/May - Latest news from KCE Trials
- 2021/April - Latest news from KCE Trials
- 2021/February - Latest news from KCE Trials
- 2019/September Latest news from KCE Trials
- 2020/February - Latest news from KCE Trials

[Read more ... >](#)

Collaboration

- International collaboration
- Clinical Trial Units (CTUs) in Belgium
- Patient and Public Involvement

Funded trials

- COV201288: Assessment of the immunogenicity

CONTACT

KCE Trials
✉ trials@kce.fgov.be

DASHBOARD TRIALS

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Today, on Clinical Trials Day, KCE Trials would like to thank the patients, researchers, healthcare professionals, and study teams who make clinical research possible. Every trial advances medical knowledge and improves patient care.

What better day to announce that the 2025 KCE Trials investigator-led call is now open!

This is a unique opportunity for clinicians and researchers in Belgium to propose their own, practice-oriented, comparative effectiveness or drug repurposing studies that are of high societal importance and have no direct commercial purpose. The full scoping criteria are available on the website : <https://lnkd.in/eNbqFp8Y>

#KCETrials #publicfunder #clinicalresearch

Vertaling weergeven



2025 investigator-led call ::



