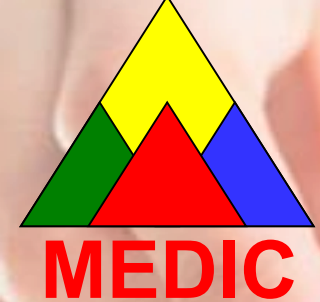




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Editorial | [Open access](#) | Published: 03 August 2026

Outcomes from the NHS-Galleri trial: the good, the bad, and the uncertain

[Nitzan Rosenfeld](#) 

[BJC Reports](#) **4**, Article number: 40 (2026) | [Cite this article](#)

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The Galleri[®] multi-cancer early detection test

Cancer screening saves lives, but 70% of cancer deaths are caused by cancers without recommended screening tests.^{*1,2} The Galleri multi-cancer early detection (MCED) test can help find these cancers. With a simple blood draw, Galleri can detect more than 50 types of cancer before symptoms appear — when they can be easier to treat and are potentially curable.³

The Galleri test does not detect a signal for all cancers and not all cancers can be detected in the blood. False positive and false negative results do occur.

The Galleri test increases the number of cancers detected seven-fold when added to standard of care screening for breast, cervical, colorectal, and lung cancers and has the lowest false positive rate of any MCED test^{**}.^{3,4,5,6}

The test is especially sensitive to many of the deadliest cancers that are typically caught too late — like pancreatic, liver, and ovarian^{***} — and about half of Galleri-detected cancers are found at an early stage.^{3,6}

The Galleri test identifies DNA in the bloodstream shed by cancer cells and does not predict future genetic risk for cancer.

The Galleri test screens for a signal shared by 50+ types of cancer³:

Adrenal Cortical Carcinoma

Ampulla of Vater

Anus

Appendix, Carcinoma

Bile Ducts, Distal

Bile Ducts, Intrahepatic

Bile Ducts, Perihilar

Bladder, Urinary

Bone

Breast

Cervix

Colon and Rectum

Esophagus and Esophagogastric Junction

Gallbladder

Gastrointestinal Stromal Tumor

Gestational Trophoblastic Neoplasms

Melanoma of the Skin

Merkel Cell Carcinoma

Mesothelioma, Malignant Pleural

Nasal Cavity and Paranasal Sinuses

Nasopharynx

Neuroendocrine Tumors of the Appendix

Neuroendocrine Tumors of the Colon and Rectum

Neuroendocrine Tumors of the Pancreas

Oral Cavity

Oropharynx (HPV-Mediated, p16+)

Oropharynx (p16-) and Hypopharynx

Ovary, Fallopian Tube and Primary Peritoneum

Small Intestine

Soft Tissue Sarcoma of the Abdomen and Thoracic Visceral Organs

Soft Tissue Sarcoma of the Head and Neck

Soft Tissue Sarcoma of the Retroperitoneum

Soft Tissue Sarcoma of the Trunk and Extremities

Soft Tissue Sarcoma Unusual Histologies and Sites

Stomach

Testis

Ureter, Renal Pelvis

Uterus, Carcinoma and Carcinosarcoma

Uterus, Sarcoma

Vagina

Vulva

Abstract

Background

Multi-cancer early detection (MCED) tests based on circulating cell-free DNA (cfDNA) methylation have emerged as a potential approach to detecting multiple cancers through a single blood test. The NHS-Galleri trial was the first randomized clinical trial to prospectively evaluate whether such screening could reduce the incidence of advanced-stage cancer.

Methods

The NHS-Galleri trial evaluated annual screening with the Galleri assay, which analyzes cancer-associated cfDNA methylation patterns and predicts the most likely Cancer Signal Origin (CSO). The prespecified primary endpoint was a reduction in the incidence of stage III–IV cancers after three years of screening. Diagnostic performance, stage distribution, and downstream diagnostic investigations were also assessed.

Results

The primary endpoint was not met, with no statistically significant reduction in stage III–IV cancer incidence within the prespecified three-year period. The episode sensitivity of Galleri was approximately 30.7% for cancers diagnosed within 12 months of testing and 54.7% for the 12 prespecified cancer types. Specificity was 99.55%, with a positive predictive value of approximately 52%. The Cancer Signal Origin was correctly predicted in approximately 92.5% of cases. The intervention group showed evidence of a shift toward earlier-stage detection for several prespecified cancers and fewer stage IV cancers, although these findings do not establish a mortality benefit. Approximately 1.2% of participants underwent additional diagnostic investigations without subsequently receiving a cancer diagnosis.

Conclusions

The NHS-Galleri trial demonstrates that cfDNA methylation-based MCED testing can identify cancer-associated signals with high specificity and may contribute to earlier-stage cancer detection. However, failure to meet the primary endpoint means that a reduction in advanced-stage cancer incidence has not been demonstrated within the study period. Moreover, stage shift alone cannot establish improved survival because of potential lead-time and related biases. Long-term follow-up and further randomized evidence are required to determine whether MCED screening translates into reductions in cancer mortality and clinically meaningful population-level benefit.

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Article | [Open access](#) | Published: 01 June 2026

Detection of *Mycobacterium tuberculosis* antigens in urinary extracellular vesicles using real-time immuno-PCR: A non-invasive diagnostic approach for pulmonary tuberculosis

[Ayushi Kaur Bedi](#) , [Bhawna Dahiya](#), [Monika Sharma](#), [Parul Mrigpuri](#), [Nitin Goel](#), [Mandira Varma-Basil](#), [Promod K. Mehta](#) & [Sadhna Sharma](#) 

[Scientific Reports](#) **16**, Article number: 24840 (2026) | [Cite this article](#)

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Abstract

Non-sputum–based diagnostics using readily available clinical samples represent an urgent need in the effort to improve tuberculosis (TB) detection and control. This study evaluated urine as a non-invasive alternative by isolating urinary extracellular vesicles (uEVs), which may facilitate the enrichment of *Mycobacterium tuberculosis* (Mtb) antigens including MPT-64 and lipoarabinomannan (LAM) being detected in this study.

A total of 162 participants were enrolled, including pulmonary TB (PTB) patients ($n = 54$), latent TB infection (LTBI) subjects ($n = 33$), other respiratory disease (ORD) controls ($n = 58$), and healthy controls ($n = 17$).

Early morning mid-stream urine samples were collected from PTB patients, individuals with ORD, LTBI cases, and healthy controls at VPCI, following standard aseptic precautions.

The uEVs were characterized using nanoparticle tracking analysis, transmission electron microscopy, and western blotting, and subsequently analyzed by real-time immuno-PCR (RT-I-PCR) for simultaneous detection of MPT-64 and LAM

The assay demonstrated ultralow limit of detection (LOD) for purified MPT-64 + LAM (9.7 fg/mL), markedly outperforming indirect ELISA (3.7 ng/mL). Clinically, RT-I-PCR demonstrated 94.44% sensitivity in bacteriologically confirmed PTB, detecting all smear- and/or culture-positive cases and 86.96% of smear- and culture-negative but GeneXpert-positive cases, with an overall specificity of 90.74% among the control groups. In comparison, indirect ELISA identified only 31.48% of bacteriologically confirmed PTB cases while maintaining a high specificity of 96.15%. Receiver operating characteristic (ROC) curve analysis of RT-I-PCR assay indicated high diagnostic accuracy, with area under the curve (AUC) values ranging from 0.9741 to 0.9847. These findings highlight the potential of uEVs-based RT-I-PCR as a highly sensitive, non-invasive approach for PTB diagnosis, while emphasizing the need for further evaluation in larger and more diverse clinical cohorts to develop a scalable, non-invasive diagnostic platform suitable for TB-endemic settings.



The NEW ENGLAND
JOURNAL of MEDICINE

ORIGINAL ARTICLE



Finerenone in Persons with Chronic Kidney Disease without Diabetes

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Published June 4, 2026 | N Engl J Med 2026;395:533-545 | DOI: 10.1056/NEJMoa2604625

VOL. 395 NO. 6 | Copyright © 2026



CME

Abstract

BACKGROUND

In randomized trials, finerenone, a nonsteroidal mineralocorticoid receptor antagonist, improved kidney and cardiovascular outcomes in patients with type 2 diabetes and chronic kidney disease (CKD). Whether finerenone has similar effects in patients without diabetes who have CKD is unknown

METHODS

We randomly assigned adults without diabetes who had CKD (estimated glomerular filtration rate [eGFR], 25 to <90 ml per minute per 1.73 m² of body-surface area) and albuminuria (urinary albumin-to-creatinine ratio, 200 to ≤3500, with albumin in milligrams and creatinine in grams) and were using a renin–angiotensin system inhibitor to receive finerenone (10 or 20 mg daily) or placebo. The primary outcome was the total eGFR slope (mean annual rate of change in the eGFR from baseline to month 32), assessed with a two-slope linear spline mixed-effects model. Secondary outcomes included a composite of kidney or cardiovascular events (reduction from baseline of at least 57% in the eGFR, kidney failure, hospitalization for heart failure, or death from cardiovascular causes), a composite of the two kidney events, and a composite of the two cardiovascular events.

RESULTS

A total of 1584 participants underwent randomization — 793 were assigned to the finerenone group, and 791 to the placebo group. The mean ($\pm$ SD) baseline eGFR was 46.8 ± 16.2 ml per minute per 1.73 m^2 with finerenone and 46.6 ± 16.0 ml per minute per 1.73 m^2 with placebo. The mean annual rate of change in the eGFR from baseline to month 32 was -3.3 ml per minute per 1.73 m^2 (95% confidence interval [CI], -3.6 to -3.1) with finerenone and -4.0 ml per minute per 1.73 m^2 (95% CI, -4.3 to -3.8) with placebo (difference, 0.7 ; 95% CI, 0.3 to 1.1 ; $P < 0.001$). Prespecified hierarchical testing showed that the risk of a composite kidney or cardiovascular outcome event was lower with finerenone than with placebo (hazard ratio, 0.77 ; 95% CI, 0.60 to 0.99 ; $P = 0.04$); the hazard ratio was 0.78 (95% CI, 0.60 to 1.01) for the composite of the two kidney events and 0.60 (95% CI, 0.27 to 1.33) for the composite of the two cardiovascular events. The most common adverse event was hyperkalemia (135 participants [17.0%] with finerenone and 105 [13.3%] with placebo); hyperkalemia events led to discontinuation of the trial regimen in 12 participants (1.5%) and 1 participant (0.1%), respectively, and to hospitalization in 7 (0.9%) and 5 (0.6%).

CONCLUSIONS

Among adults with CKD who did not have diabetes, finerenone led to a slower decrease in the eGFR than placebo over 32 months.

- Finerenone là kháng thụ thể mineralocorticoid không steroid (non-steroidal MRA), gắn chọn lọc vào mineralocorticoid receptor (MR) và ức chế hoạt hóa MR bởi aldosterone và cortisol, giảm quá trình viêm, xơ hoá, tổn thương nội mô mạch máu qua trung gian MR, từ đó làm giảm tổn thương thận - tim mạch.
- Khác với spironolactone/eplerenone, finerenone không phải steroid, có tính chọn lọc MR cao và phân bố tương đối cân bằng giữa tim và thận. Vì vậy, tác dụng chính được kỳ vọng là cardiorenal protection chứ không phải lợi tiểu.
- Các chỉ định kê toa đã được phê duyệt cho đến thời điểm hiện tại:
 - Đái tháo đường type 2 + uACR > 30mg/g
 - Đái tháo đường type 1 + uACR > 30mg/g (phê duyệt ngày 17/09/2026)
 - Suy tim với EF $\geq 40\%$
- Tác dụng phụ: tăng Kali máu, ít gặp: hạ huyết áp, hạ Natri máu, mất nước.
- Không khuyến cáo khởi trị Finerenone ở bệnh nhân có eGFR <25 ml/min/1.73m²





Rapid Kidney Function Testing for Early Disease Detection

Nova Max Pro Creatinine/eGFR is an innovative meter and biosensor designed to improve kidney care through early detection of kidney disease, enabling timely treatment. It delivers fast, accurate results and is simple to use, with a process similar to a glucose meter for diabetes. Using a small capillary fingerstick sample, Nova Max Pro reports creatinine and estimated glomerular filtration rate (eGFR) in just 30 seconds, calculated with the CKD-EPI equation (with or without race as a factor). Test results can be wirelessly transmitted to Bluetooth-enabled applications for review and intervention by healthcare professionals.





Proven Accuracy

Validated by clinical evidence and gold-standard comparisons

The Nova Max Pro meter incorporates Nova Biomedical's advanced sensor technology, utilizing the same StatSensor® Creatinine enzymatic technology that has been trusted in hospital point-of-care meters for over 15 years. In a 2021 university medical center study of 670 patients sponsored by the International Society of Nephrology, this technology proved more accurate than the laboratory Jaffe Creatinine/eGFR method when both were compared to the gold standard measured GFR (mGFR). By leveraging this proven technology, Nova Max Pro delivers hospital-grade accuracy in a handheld format for point-of-care testing.

DE GRUYTER

Clin Chem Lab Med 2021; asp

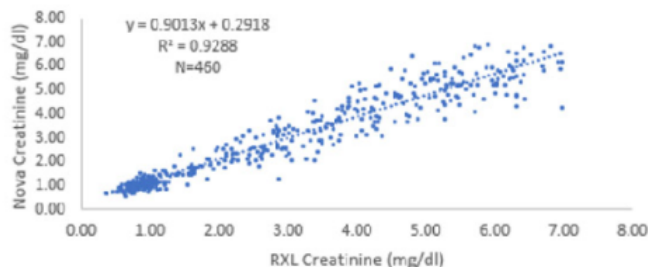


Sean Currin*, Mwawi Gondwe, Nokthula Mayindi, Shingirai Chipungu, Bongekile Khoza, Lungile Khambule, Tracy Snyman, Stephen Tollman, June Fabian and Jaya George, on behalf of the ARK Consortium

Evaluating chronic kidney disease in rural South Africa: comparing estimated glomerular filtration rate using point-of-care creatinine to iohexol measured GFR



Nova Max Pro vs Siemens Dimension RxL



Strong Correlation to Hospital Lab Analyzer

In a study performed for regulatory submission, 517 patients at three different sites had Nova Max Pro Creatinine eGFR tests performed on fingerstick capillary blood samples. At the same time a venous blood sample was drawn and a laboratory analysis of creatinine/eGFR was performed. The creatinine method correlation is shown above.

Great Method Precision

Creatinine within-run and day-to-day precision studies were performed at three creatinine levels. 120 replicates of whole blood were used to calculate within-run precision and 240 replicates of controls were used to calculate day-to-day precision. The creatinine SD and CV% are shown below above.

Day-to-Day Precision, Controls				Within Run Precision, Whole Blood			
	Level 1	Level 2	Level 3		Level 1	Level 2	Level 3
N	240	240	240	N	120	120	120
Mean (mg/dL)	1.5	3.4	5.5	Mean (mg/dL)	1.5	3.4	5.5
SD/CV%	0.13	5.3%	4.5%	SD/CV%	0.08	5.4%	4.0%

Sensitivity 98.9% (357/361)

Specificity 85% (133/156)

True Positives = 357

False Positives = 23

True Negatives = 133

False Negatives = 4

High Sensitivity and Specificity

Sensitivity is the ability of a method to detect patients with the disease and specificity is the ability to detect patients without the disease. Patients with an eGFR >60 ml/min/1.73m² are considered to have normal kidney function, patients with eGFR <60 ml/min/1.73m² are considered to have kidney disease. Nova Max Pro uses the CKD-EPI equation to calculate eGFR. The results from this 517-patient study are shown above.

Tozorakimab demonstrated statistically significant and highly clinically meaningful reduction in COPD exacerbations in OBERON and TITANIA Phase III trials

PUBLISHED

8 September 2026

Tozorakimab showed clinically meaningful benefits across blood eosinophil thresholds

Full results published in the New England Journal of Medicine and presented at the European Respiratory Society Congress 2026

Tozorakimab Biologics License Application accepted under Priority Review in US for patients with COPD

Background

Chronic obstructive pulmonary disease (COPD) is characterized by persistent airflow limitation, chronic airway inflammation, and recurrent exacerbations. Despite optimized inhaled maintenance therapy, a substantial proportion of patients continue to experience moderate or severe exacerbations. Interleukin-33 (IL-33) is an upstream mediator of type 2 and non-type 2 inflammatory pathways and has also been implicated in airway epithelial dysfunction and mucus abnormalities. Tozorakimab is a fully human monoclonal antibody targeting IL-33, designed to inhibit signaling from both reduced and oxidized forms of IL-33.

Methods

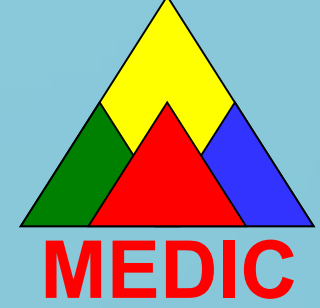
OBERON and TITANIA were randomized, double-blind, placebo-controlled Phase III trials evaluating tozorakimab in adults with symptomatic, exacerbation-prone COPD despite maintenance inhaled therapy. A total of 2,306 patients with ≥ 2 moderate or ≥ 1 severe exacerbation in the previous 12 months were randomized to subcutaneous tozorakimab 300 mg or placebo every 4 weeks for 52 weeks, alongside standard inhaled therapy. The primary endpoint was the annualized rate of moderate-to-severe COPD exacerbations in former smokers, with the overall current/former smoker population assessed as a key secondary endpoint.

Results

Tozorakimab significantly reduced the annualized rate of moderate-to-severe COPD exacerbations compared with placebo in both replicate Phase III trials. Among former smokers, the primary population, tozorakimab reduced moderate-to-severe exacerbations by 29% in OBERON and 34% in TITANIA compared with placebo. In the overall population of current and former smokers, the corresponding reductions were 30% in OBERON and 29% in TITANIA. The treatment effect was observed across prespecified subgroups, including different blood eosinophil categories. In the pooled analysis of OBERON and TITANIA, the reduction in moderate-to-severe exacerbations was approximately: 23% among patients with baseline blood eosinophil counts <150 cells/ μL ; 34% among patients with counts ≥ 150 cells/ μL ; and 43% among patients with counts ≥ 300 cells/ μL . These findings suggest that the efficacy of tozorakimab was not restricted to patients with an eosinophilic phenotype, although the magnitude of benefit appeared greater at higher eosinophil concentrations. An integrated analysis additionally demonstrated a reduction in mucus plugging, supporting a potential effect of IL-33 inhibition on airway epithelial dysfunction and mucus abnormalities in COPD.

Conclusion

In the replicate Phase III OBERON and TITANIA trials, tozorakimab 300 mg administered every four weeks significantly reduced moderate-to-severe COPD exacerbations compared with placebo when added to inhaled maintenance therapy. The treatment effect was demonstrated in both former smokers and the broader population of current and former smokers and was observed across prespecified blood eosinophil subgroups. Together with the reduction in mucus plugging and the reported favorable safety profile, these findings support further development of IL-33 inhibition as a biologic treatment strategy for exacerbation-prone COPD.



**THANK YOU
FOR LISTENING**