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Contract

PURCON924 - PUFA IMP and Placebo

University of East Aglia

F03: Contract award notice
Notice identifier: 2021/S 000-008908
Procurement identifier (OCID): ocds-h6vhtk-029840
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Section I: Contracting authority

I.1) Name and addresses

University of East Aglia

Centrum

Norwich

NR47UG

Contact

Sonny Gardiner

Email

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Telephone

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Country

United Kingdom

NUTS code

UKH - East of England

Internet address(es)

Main address

https://in-tendhost.co.uk/universityofeastanglia/aspx/Tenders/MyTenders

I.4) Type of the contracting authority

Other type

University

I.5) Main activity

Education

Section II: Object

II.1) Scope of the procurement

II.1.1) Title

PURCON924 - PUFA IMP and Placebo

II.1.2) Main CPV code

- 33000000 - Medical equipments, pharmaceuticals and personal care products

II.1.3) Type of contract

Supplies

II.1.4) Short description

We are looking to contract with a manufacturer who can:

• Provide active Omacor capsules of n-3 PUFA (eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) in 1g capsules in a 1.3:1 ratio in accordance with specified regulations;

• Manufacture matched placebo (palm oil and soybean oil) soft-gel capsules in an 8:2 ratio in accordance with specified regulations;

• Bottle and label trial medication in accordance with specified regulations;

• QP release the active and placebo capsules with a minimum shelf life of 12 months; and

• Either, ship final trial medication direct to participants following dispensing centrally OR ship to recruiting site pharmacies for dispense and onward shipping.

The efficacy and mechanisms of action of n-3 poly-unsaturated fatty acid supplementation in people with non-steroidal exacerbated airways disease and uncontrolled asthma (PUFA): placebo-controlled randomised parallel multi-centre clinical trial is due to commence recruitment in July 2021. The trial will be conducted according to Good Clinical Practice and Medicines and Healthcare products Regulatory Agency regulations. The trial is Sponsored by the Norfolk and Norwich University Hospitals NHS Foundation Trust (NNUH) with specified tasks delegated to the University of East Anglia (UEA). The UEA Norwich Clinical Trials Unit (NCTU) is a UKCRC registered trials unit and works with sites and institutes across the UK to deliver high quality studies. PUFA is a National Institute of Health Research project funded by the Efficacy and Mechanism Evaluation programme

(NIHR number: 129910).

PUFA aims to determine whether n-3 poly-unsaturated fatty acid supplementation in people with non-steroidal exacerbated respiratory disease (N-ERD) can improve asthma control as measured by the asthma control questionnaire. A total of 98 participants from NHS Trusts across the UK will be recruited and complete study assessments at 3 monthly intervals for a total of 6 months. Recruitment is anticipated to last 15 months, completing in October 2022. Participants will be recruited throughout this period.

Participants will be randomised to receive either 6g / day of n-3 PUFA (eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) as 6 Omacor capsules (5.04g EPA + DHA) or matched soft-gel placebo (palm oil and soybean oil) capsules, to be taken once daily or in divided doses with food for 6 months.

The active treatment will be administered as 6g of EPA and DHA in a 1.3:1 ratio as six Omacor capsules. Active capsules will comprise 84% EPA + DHA. Active capsules should not be altered in any way i.e. must not be overencapsulated. Placebo treatment will comprise 6 soft-gel capsules containing palm oil and soybean oil in an 8:2 ratio. Placebo capsules must appear identical to the active capsules.

Trial treatment will be dispensed in bottles to each participant once during their involvement in the trial.

We anticipate that 58,900 active capsules and 58,900 placebo capsules will be dispensed in total.

Trial medication will need to be produced by a company with a current MIA(IMP) license and in accordance with Good Manufacturing Practice as described in Rules and Guidance for Pharmaceutical Manufacturers and Distributors 2014 (Sub-section 2, Part 1, Annex 13). Trial medication will need be certified by a qualified person prior to release and labelled in accordance with Directive 2003/94/EC and Good Manufacturing Practice as described in Rules and Guidance for Pharmaceutical Manufacturers and Distributors 2014 (Sub-section 2, Part 1, Annex 16).

The final trial medication will be shipped directly to participants homes. This may be direct to participant from the manufacturer or via the local NHS pharmacies. We are happy for suppliers to quote for either both or just one of these methods.

II.1.6) Information about lots

This contract is divided into lots: No

II.2) Description

II.2.3) Place of performance

NUTS codes

- UKH - East of England

II.2.4) Description of the procurement

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• Manufacture matched placebo (palm oil and soybean oil) soft-gel capsules in an 8:2 ratio in accordance with specified regulations;

• Bottle and label trial medication in accordance with specified regulations;

• QP release the active and placebo capsules with a minimum shelf life of 12 months; and

• Either, ship final trial medication direct to participants following dispensing centrally OR ship to recruiting site pharmacies for dispense and onward shipping.

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II.2.5) Award criteria

Price

II.2.11) Information about options

Options: No

Section IV. Procedure

IV.1) Description

IV.1.1) Type of procedure

Open procedure

IV.1.8) Information about the Government Procurement Agreement (GPA)

The procurement is covered by the Government Procurement Agreement: Yes

IV.2) Administrative information

IV.2.1) Previous publication concerning this procedure

Notice number: 2021/S 000-004326

Section V. Award of contract

A contract/lot is awarded: No

V.1) Information on non-award

The contract/lot is not awarded

No tenders or requests to participate were received or all were rejected

Section VI. Complementary information

VI.4) Procedures for review

VI.4.1) Review body

University of East Anglia

Norwich

Country

United Kingdom