ViKEM

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Main Information

Primary registry identifying number
LBCTR2023075403

Protocol number
MK7-003

MOH registration number

Study registered at the country of origin
Yes

Study registered at the country of origin: Specify

Type of registration
Prospective

Type of registration: Justify
N/A

Date of registration in national regulatory agency
24/07/2023

Primary sponsor
Sola Aoun Bahous

Primary sponsor: Country of origin
Lebanon

Date of registration in primary registry
06/02/2024

Date of registration in national regulatory agency
24/07/2023

Public title
ViKEM

Acronym

Scientific title
Vitamin K2 Supplementation in Adult Episodic Migraine

Acronym

Brief summary of the study: English

Migraine is a debilitating illness and a major cause of disability in the world. It is highly prevalent, especially among women. Vitamin supplementation is a potential therapeutic option for migraines that remains largely under-explored. Several studies have shown that people with migraine tend to have higher arterial stiffness than people without migraine. Vitamin K2 deficiency is an important mediator of arterial stiffness and calcification due to decreased carboxylation of matrix Gla protein (MGP). Supplementation reverses these changes and improves vascular health in patients with end stage renal disease according to previous studies. Therefore, vitamin K2 supplementation could serve a potential role in migraine patients. The purpose of the study is to test the effect of vitamin K2 on decreasing the frequency of migraines and decreasing arterial stiffness. The population will be recruited from the neurology clinic at LAU Medical Center-Rizk Hospital and will constitute of adult patients . They will be randomized to receive either the supplement of vitamin K2 or a placebo for the duration of 6 months. Lab tests and arterial stiffness measurements will be done at the beginning, middle, and at the end of the study for comparison.

Brief summary of the study: Arabic

مكملات الفيتامينات هي خيار علاجي غير مستكشف للمرضى الذين يعانون من الصداع النصفي. أدركت العديد من الدراسات دور التغيرات دوراً في تحسين صحة الأوعية الدموية من دون أثار جانبية سلبية مهمة أو K2 الوعائية في تطور الصداع النصفي. تبين سابقاً أن للفيتامين تفاعل سلبي مع أدوية أخرى. أيضاً، تبين أن الأشخاص الذين يعانون من الصداع النصفي يعانون من نقص في مستوى فيتامين (ك) وارتباط مباشر بين هذا النقص وزيادة تصلب الشرايين.
خلال ستة أشهرمن التناول في تحسين نوبات الصداع النصفي وتحسين صحة الأوعية الدموية عند مرضى2تهدف دراستنا تقييم دور الفيتامين ك يتم قياس صحة الأوعية الدموية عن طريق .(LAUMC-RH) تعاني من الصداع في المركز الطبي للجامعة اللبنانية الأميركية - مستشفى رزق و الشريان (Femoral Artery) بين الشريان الفخذي (Pulse Wave Velocity) تقنية غير غازية تقيس سرعة موجة النبض في الدم و K2 بهدف معرفة مدى سرعة تدفق الدم في الشرايين الرئيسية و أيضاً عن طريق قياس معدل الفيتامين السباتي(Carotid Artery) معدل بروتينات أخرى تدل على صحة الشرايين في الدم. سنقوم بتقييم أيضا دور عوامل أخرى قد تكون مرتبطة بقياس سرعة موجة النبض أو معدل فيتامين K2 مشارك في هذه الدراسة120في الدم عند هؤلاء المرضى. نأمل في تسجيل حوالي .

مدة الدراسة:
• أشهر٦تستغرق هذه الدراسة حوالي .

Health conditions/problem studied: Specify

Episodic migraine headache among adult subjects.

Interventions: Specify

Vitamin K2 (MenaQ7) vs. Placebo for 6 months

Key inclusion and exclusion criteria: Inclusion criteria

Inclusion criteria: adults subjects, history of episodic migraine with or without aura since > 12 months according to the ICHD-3 criteria, migraine frequency from 4-14 days per month over the 3 months prior to screening, migraine frequency from 4-14 days per month during the baseline period of assessment, successful completion of the migraine diary during the baseline evaluation period.

Key inclusion and exclusion criteria: Gender

Both

Key inclusion and exclusion criteria: Specify gender

Key inclusion and exclusion criteria: Age minimum

18

Key inclusion and exclusion criteria: Age maximum

100

Key inclusion and exclusion criteria: Exclusion criteria

Exclusion criteria: migraine patients with superimposed tension type or other forms of primary headaches, patients who are currently on any of the migraine prophylactic treatments (sodium valproate, topiramate, beta-blockers, tricyclic antidepressants, SRNI, flunarizine, verapamil, lisinopril, candesartan), patients who have been on any of the previously listed medications within 3 months of screening, patients who take the following medications: ergotamine or triptans > 10 days per month, NSAIDs or paracetamol > 15 days per month, opioids more than 4 days per month, patients on oral vitamin K antagonists, other active chronic pain syndromes (i.e. fibromyalgia, painful peripheral neuropathy, postherpetic neuralgia…), history of hypersensitivity to the vitamin K2, history of soy protein allergy, history of thrombotic events, diagnosed coagulopathy, cardiovascular event in the past month, current or planned pregnancy, lactation, inability to tolerate oral medications, known intestinal malabsorption or hypomotility syndromes, atrial fibrillation, active malignancy. or acute illness in the past month.

Type of study

Interventional

Type of intervention

Pharmaceutical

Type of intervention: Specify type

N/A

Trial scope

Therapy

Trial scope: Specify scope

N/A

Study design: Allocation

Randomized controlled trial

Study design: Masking

Blinded (masking used)

Study design: Control

Placebo

Study phase

N/A

Study design: Purpose

Treatment

Study design: Specify purpose

N/A

Study design: Assignment

Parallel

Study design: Specify assignment

N/A

IMP has market authorization

IMP has market authorization: Specify

Yes, Lebanon and Worldwide

Lebanon

Name of IMP

MenaQ7

Year of authorization

Month of authorization

Type of IMP

Others

Pharmaceutical class

Supplement/Vitamin - Menaquinone

Therapeutic indication

Episodic migraine headache

Therapeutic benefit

Possible improvement in migraine attacks and arterial stiffness.

Study model

N/A

Study model: Explain model

N/A

Study model: Specify model

N/A

Time perspective

N/A

Time perspective: Explain time perspective

N/A

Time perspective: Specify perspective

N/A

Target follow-up duration

Target follow-up duration: Unit

Number of groups/cohorts

Biospecimen retention

None retained

Biospecimen description

Blood samples will be drawn for tests. urine will be collected for analysis.

Target sample size

160

Actual enrollment target size

Date of first enrollment: Type

Anticipated

Date of first enrollment: Date

03/09/2023

Date of study closure: Type

Anticipated

Date of study closure: Date

02/09/2024

Recruitment status

Recruitment status: Specify

Pending

Date of completion

IPD sharing statement plan

Yes

IPD sharing statement description

We will be ready to share data upon request.

Additional data URL

Admin comments

Trial status

Approved

Secondary Identifying Numbers

Full name of issuing authority	Secondary identifying number
ClinicalTrials.gov	NCT05943457

Sources of Monetary or Material Support

Name
Lesaffre International

Secondary Sponsors

Name
Omicron Pharmaceuticals

Contact for Public/Scientific Queries

Contact type	Contact full name	Address	Country	Telephone	Email	Affiliation
Public	Sola Aoun Bahous	Lebanese American University	Lebanon	+9613259 450	sola.bahous@lau.edu.lb	Lebanese American University
Scientific	Sola Aoun Bahous	Lebanese American University	Lebanon	+9613259 450	sola.bahous@lau.edu.lb	Lebanese American University

Centers/Hospitals Involved in the Study

Center/Hospital name	Name of principles investigator	Principles investigator speciality	Ethical approval
Lebanese American University Medical Center-Rizk Hospital	Sola Aoun Bahous	Nephrology	Approved

Ethics Review

Ethics approval obtained	Approval date	Contact name	Contact email	Contact phone
Lebanese American University- University Medical Center Rizk Hospital	02/12/2022	Joseph Stephan	joseph.stephan@lau.edu.lb	+96176660166

Countries of Recruitment

Name
Lebanon

Health Conditions or Problems Studied

Condition	Code	Keyword
Episodic migraine	Migraine (G43)	Migraine

Interventions

Intervention	Description	Keyword
Menaquinone	360 mcg/d of menaquinone-7 (MenaQ7; NattoPharma, Hovik, Norway) for 6 months.	MenaQ7

Primary Outcomes

Name	Time Points	Measure
Changes of monthly migraine days	6 months	aquestionnaire to be administered at the start, monthly, and at the end of the study (6months) about frequency and number of migraine days per month.

Key Secondary Outcomes

Name	Time Points	Measure
Changes from baseline in the headache impact score	3 & 6 months	HIT-6
Changes from baseline in monthly severe migraine days	3 & 6 months	visual analogue rating scale
Changes from baseline on the modifi ed migraine disability assessment	3 & 6 months	MIDAS
Changes from baseline on the modified migraine physical function impact diary	3 & 6 months	MPFID
Changes from baseline on the quality of life	3 & 6 months	EuroQoL
Changes of arterial stiffness level	3 & 6 months	cfPWV

Trial Results

Summary results

Study results globally

Date of posting of results summaries

Date of first journal publication of results

Results URL link

Baseline characteristics

Participant flow

Adverse events

Outcome measures

URL to protocol files