Survey of pharmacists to evaluate the effectiveness of the Viagra Connect national additional Risk Minimisation Measure (aRMM) in the United Kingdom (UK) (NA)

First published: 28/12/2018

Last updated: 14/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS27346

Study ID

32208

DARWIN EU® study

No

Study countries

United Kingdom

Study description

This study will be conducted per request of the UK's MHRA (Medicines and Healthcare Products Regulatory Agency). The study will be a cross sectional, non interventional web based survey that will be conducted among pharmacists in the UK. The objective of the study is to evaluate the effectiveness of the Viagra Connect national aRMMs (i.e. the pharmacist training guide and the checklist) by assessing: • The pharmacists' knowledge of the key risk messages contained in the Viagra Connect training materials, • The pharmacists' participation in the Viagra Connect pharmacist training,• The pharmacists' utilisation of the optional Viagra Connect Pharmacy Checklist at the point of dispensing. Pharmacists must meet all of the following inclusion criteria to be eligible for inclusion in the study:• Willing/consent to participate in this self administered survey, • A practicing pharmacist in the UK, • Received at least one patient face-to-face request to supply Viagra Connect in the past six months.

Study status

Finalised

Research institutions and networks

Institutions

United BioSource Corporation (UBC)

Switzerland

First published: 25/04/2013

Last updated: 06/03/2024

Institution | Non-Pharmaceutical company | ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Joanna (Asia) Lem

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 27/09/2017

Actual: 27/09/2017

Study start date

Planned: 31/01/2019

Actual: 31/01/2019

Data analysis start date

Planned: 01/05/2019

Actual: 01/04/2019

Date of final study report

Planned: 31/07/2019

Actual: 23/07/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer

Study protocol

Viagra Connect_A1481334_PASS_Pharmcist Survey_Protocol_Redacted for ENCeP registration.pdf (1019.05 KB)

A1481334_FINAL PROTOCOL AMENDMENT 2 (V.1.2)_13JUNE2018.doc.pdf (2.15 MB)

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Other study registration identification numbers and links

Study Protocol Number: A1481334

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

To evaluate the effectiveness of the Viagra Connect national aRMM by assessing: • The pharmacists’ knowledge of the key risk messages contained in the Viagra Connect training materials, • The pharmacists’ participation in the Viagra Connect pharmacist training,• The pharmacists’ utilisation of the optional Viagra Connect Pharmacy Checklist at the point of dispensing.

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(G04BE03) sildenafil

sildenafil

Medical condition to be studied

Erectile dysfunction

Population studied

Short description of the study population

Pharmacists who have received at least one patient request to supply Viagra Connect within the six months preceding the survey administration.
Pharmacists must meet all of the following inclusion criteria:
1. Willing/consent to participate in this self-administered survey (Answered “Yes” to a survey question asking “Do you agree to proceed with this survey”);
2. A practicing pharmacist in the UK;
3. Received at least one patient face-to-face request to supply Viagra Connect in the past six months.

Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Estimated number of subjects

200

Study design details

Data analysis plan

Data collected from the survey will be reported as descriptive statistics. No statistical inferences will be made. Frequency distributions with 95% confidence intervals (CIs) will be calculated for pharmacist's responses to all questions that address the survey objectives. Survey data will be stratified by participating in the training and by other key pharmacist's characteristics if sample sizes are large enough (ie, no less than 25 in the minority group).

Documents

Study results

a1481334-report-body.pdf (4.81 MB)

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data sources (types)

Other

Data sources (types), other

Cross-sectional survey of pharmacists

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No