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

PURI
https://redirect.ema.europa.eu/resource/32208

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 institution 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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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

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

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

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