Impact of withdrawal of fusafungine from the market on the prescribing of alternative treatments in Germany

Study protocol

Data source and study population

Version June 2017 of IMS® Germany, which contains anonymised medical records from a representative panel of GPs, specialists in internal medicine and other specialist physicians in computerized practices throughout Germany since 1992, will be analysed. The study period will be from 29 May 2013 to 28 May 2017, including three years before and one year after the withdrawal of fusafungine. The study will include the most common prescribers of fusafungine. The most common upper respiratory airways disease diagnoses (URAD) in patients prescribed fusafungine will be identified. Practices to be included in the study are those which have prescribed fusafungine in at least 0.5% of all patients and at least 5% of patients with a selected URAD during each of the three years prior to the withdrawal of fusafungine. Control practices with no prescribing of fusafungine during the study period will also be included.

Study design

Results will be analysed by speciality. The following treatments on the day of the URAD diagnosis will be investigated in patients with a selected URAD:

1. Treatment with systemic antibiotics
2. Treatment with fusafungine
3. Treatment with tyrothricin
4. Treatment with other nasal and throat preparations (other N&Ts)
5. No treatment

The treatments are defined as mutually exclusive groups where group 2 excludes group 1 and so on. The proportion of URAD consultations for each treatment pathway will be analysed quarterly.

Exposures

Fusafungine and tyrothricin containing products will be identified by substance name. Other N&Ts will be identified by EphMRA ATC codes R01A (topical nasal preparations), R01B (systemic nasal preparations), and R02A (throat preparations, excluding products containing fusafungine or tyrothricin). Systemic antibiotics will be identified by EphMRA ATC codes J01A (tetracyclines and combinations), J01B (chloramphenicol and combinations), J01C (broad-spectrum penicillins), J01D (cephalosporins), J01E (trimethoprim and similar preparations), J01F (macrolides and similar types), J01G (fluoroquinolones), J01H (plain medium and narrow spectrum penicillins and penicillin/streptomycin combinations), J01K (aminoglycosides), J01L (carbenicillin and similar types), J01P (other beta-lactam antibacterials excluding penicillins and cephalosporins), and J01X (other antibacterials).

In each speciality, the three most common URAD diagnoses as determined by ICD 10 diagnosis codes on the day of the fusafungine prescription will be selected.

Data analysis

An interrupted time series regression analysis will be used to evaluate statistically the effect of the withdrawal on treatment pathways in patients with selected URAD, comparing the four quarters after the withdrawal with the 12 previous quarters. This will be done using linear regression. Included fusafungine-prescribing practices will be compared to practices with no fusafungine prescribing.