ISRCTN11747547 https://doi.org/10.1186/ISRCTN11747547

Can providing real-time warnings and feedback to physicians within a hospital information system reduce inappropriate glucocorticoid prescription?

Submission date
30/11/2021

Recruitment status
No longer recruiting

Registration date
02/12/2021

Overall study status
Completed

Last Edited
10/01/2024

Condition category
Other

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Background and study aim
Glucocorticoids are powerful medicines that fight inflammation and work with the immune system to treat a wide range of health problems. They are one of the most commonly used drugs in clinics. However, excessive use of glucocorticoids can lead to many adverse reactions. Therefore, regulating the use of glucocorticoids is of great significance in promoting human health and reducing the burden of disease. Previous studies have shown that improper use of glucocorticoids is serious in China, especially in primary health care institutions, due to outdated and inadequate knowledge and training of doctors in rural China.
This intervention aims to establish a continuous feedback learning system for standardized use of glucocorticoids and an intelligent ideal treatment plan through the combination of the Chinese Health information system (HIS) and gradient boosted decision tree (GBDT) technology in artificial intelligence technology (AI), so that the HIS can prompt and suggest rational drug use by primary care physicians. This study will provide effective feedback and suggestions on the rational use of glucocorticoids for primary medical institutions in Guizhou Province, and effectively reduce the unreasonable use of glucocorticoids.

Who can participate?
Doctors working in one of the 78 hospitals under investigation, who write at least 100 prescriptions every 10 days.

What does the study involve?
The primary care institutions will be randomly divided into two groups. One group will have the real-time warnings and feedback available within its hospital information system for 3 months and will then have it will go into the control group, while the other group will have a 3-month period without the real-time warnings and feedback and will then have 3 months with these features.

What are the possible benefits and risks of participating?
None

Where is the study run from?
Guizhou Medical University (China)

When is the study starting and how long is it expected to run for?
November 2021 to December 2023

Who is funding the study?
The Science and Technology Department of Guizhou Province (China)

Who is the main contact?
Prof Yue Chang, 342888764@qq.com

Contact information

Type(s)
Scientific

Contact name
Prof Yue Chang

ORCID ID
http://orcid.org/0000-0003-1048-6932

Contact details
Guizhou Medical University
Guiyang
China
550025
+86-13312270062
342888764@qq.com

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
ZK [2021]499

Study information

Scientific Title

Feedback intervention model of gradient boosted decision tree (GBDT) for glucocorticoid prescription control in primary care institutions: a cross-over randomized controlled trial

Study objectives

This intervention aims to increase rational usage of glucocorticoids based on collaboration among local health management authorities, practicing rural physicians, medical experts, and IT experts.
Glucocorticoids are one of the commonly used clinical drugs in China for anti-inflammatory, anti-toxic, anti-shock, and immunosuppression. However, excessive use of glucocorticoids can lead to side effects, such as osteoporosis, spontaneous fractures, steroid-induced diabetes, immune defense, irritation exacerbating infection, and increased difficulty in treatment. Therefore, it is important to regulate the usage of glucocorticoids to promote human health and reduce the burden of disease. Previous studies have shown that irrational use of glucocorticoids is serious in China, especially in primary care institutions. Although the Chinese government has provided policies and guidelines to regulate the usage of glucocorticoids, these measures have no obvious effect in reducing glucocorticoids prescription rates. Approximately 900 million farmers in China are currently under the primary care services, which are provided by rural physicians. However, despite the rapid development of Chinese medicine in recent years, millions of farmers still do not meet the requirements of rational usage of medicines.
Physicians in China use a medical computing network. The intervention will be conducted in Guizhou province, one of China's poorest regions, and will involve physicians from 78 primary care institutions. In the Chinese Health information system (HIS), a computer deep learning system for the standardized use of glucocorticoids and an intelligent ideal treatment plan was established by using gradient-boosted tree technology in artificial intelligence technology. HIS automatically prompts and suggests rural physicians to use drugs properly when rural physicians prescribe irrational glucocorticoids or overprescribe. It is expected that the use of glucocorticoids in primary care institutions will be reduced through this automatic early warning intervention system and provide a feasible reference for addressing the problem of glucocorticoid abuse. It is hoped that this approach will spread to other rural areas in China.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 30/11/2021, Ethics Committee of Guizhou Medical University (Guizhou Medical University, Guian new district, Guizhou Province, China; +86 0851-88416075; 251982143@qq.com), ref: 2021(249)

Study design

Non-blinded cluster-randomized crossover controlled trial

Primary study design

Interventional

Secondary study design

Randomised cross over trial

Study setting(s)

Hospital

Study type(s)

Other

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Prescription of glucocorticoids for common infectious diseases in primary care institutions

Interventions
A randomized crossover controlled trial (multicenter) will be conducted in 78 primary care institutions randomly selected from HIS. The primary care institutions will be randomly divided into two groups. One group will have the real-time warnings and feedback available within its hospital information system for 3 months and will then have it will go into the control group, while the other group will have a 3-month period without the real-time warnings and feedback and will then have 3 months with these features.
By using GBDT technology in artificial intelligence, we will establish early warning feedback intervention in HIS. The early-warning feedback methods can be divided into the following two categories:
1. AI-based real-time warning pop-up windows of improper glucocorticoid use.
Based on the HIS system of the primary care institutions, the warning plug-in uses GBDT technology to automatically access the prescription data in the background. It will compare each prescription with GBDT modeling results, determine whether the glucocorticoids prescription (including type, dosage, and course of treatment) is reasonable to be used in the consultation service, and will provide a real-time automatic warning alert for unreasonable glucocorticoids prescription. Once a physician prescribes an unreasonable glucocorticoid, a pop-up window will automatically appear in the lower right corner of the screen to alert the physician that the prescription is unreasonable and indicate the type of unreasonable use of glucocorticoids. The pop-up window will disappear if the physician clicks on it. It will also automatically disappear after 5 minutes. The duration of the pop-up window will be recorded automatically by the system. We define unreasonable prescription of glucocorticoids with the following indicators: 1. inappropriate indications; 2. inappropriate drug selection; 3. inappropriate drug dosage form or route of administration; 4. inappropriate drug combination or incompatibility; 5. drug combination is not suitable or incompatibility is contraindicated; 6. repeated administration; 7. physician's use of glucocorticoids beyond authorization; 8. other abuses.
2. Warning of high glucocorticoids prescription rate.
The system will appear on the physician's screen in the form of an automatic pop-up window every 10 days, informing them of their ranking in terms of their glucocorticoids prescription rate within the same outpatient department, actual glucocorticoids prescription rate, and related information. The information seen by each physician will be confidential. The physicians have the freedom to read this feedback message or not. When the physician logs into the HIS, a pop-up window or link will appear on the computer screen, prompting him or her to view the message. If a physician presses the ESC button, it will disappear. All the on-screen procedures, including the click rate and the time of the message, will be recorded automatically.

Intervention Type
Behavioural

Primary outcome measure
The 10-day glucocorticoid prescriptions rate of the physicians, defined as the number of glucocorticoid prescriptions divided by the total number of prescriptions in each 10-day time

period. A ‘prescription' refers to each glucocorticoid. The glucocorticoid prescription rate is assessed using hospital pharmacy stock records during the 3-month intervention period.

Secondary outcome measures
The rational rate of glucocorticoid prescription, defined as the reasonable number of glucocorticoids prescribed during the study period divided by the total amount of glucocorticoids prescribed throughout the study period

Overall study start date
30/11/2021

Completion date
31/12/2023

Eligibility

Key inclusion criteria
1. Have the same HIS system
2. 78 public primary hospitals with more than 3 outpatient doctors who can write 100 prescriptions every 10 days on average and who have been working continuously for at least 1 year

Participant type(s)
Health professional

Age group
Adult

Sex
Both

Target number of participants
320

Total final enrolment
347

Key exclusion criteria
1. Do not meet inclusion criteria
2. Do not have the right to prescribe
3. Refuse to accept intervention

Date of first enrolment
01/06/2022

Date of final enrolment
01/06/2023

Locations

Countries of recruitment
China

Study participating centre
Guizhou Medical University
Guizhou
Guiyang
China
550025

Sponsor information

Organisation
Guizhou Medical University

Sponsor details
Guian New Area University Town
Guiyang
China
550025
+86-13608538065
4567401@qq.com

Sponsor type
University/education

Website
http://www.gmc.edu.cn

Funder(s)

Funder type
Government

Funder Name
Guizhou Science and Technology Department

Alternative Name(s)
Guizhou Science and Technology Department, Guizhou Science and Technology Department, , Science and Technology Foundation of Guizhou Province, Department of Science and Technology of Guizhou Province, Department of Science and Technology, Guizhou Province

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
China

Results and Publications

Publication and dissemination plan
Planned publication of 1-2 manuscripts in high-impact peer-reviewed journals.

Intention to publish date
31/12/2024

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		05/01/2024	10/01/2024	Yes	No