Systematic review

Please complete all mandatory fields below (marked with an asterisk *) and as many of the non-mandatory fields as you can then click Submit to submit your registration. You don't need to complete everything in one go, this record will appear in your My PROSPERO section of the web site and you can continue to edit it until you are ready to submit. Click Show help below or click on the icon to see guidance on completing each section.
This record cannot be edited because it has been rejected


Give the working title of the review, for example the one used for obtaining funding. Ideally the title should state succinctly the interventions or exposures being reviewed and the associated health or social problems. Where appropriate, the title should use the PI(E)COS structure to contain information on the Participants, Intervention (or Exposure) and Comparison groups, the Outcomes to be measured and Study designs to be included.

Cardiovascular safety associated with SGLT-2 inhibitors across racial groups in patients with type 2 diabetes mellitus: a meta analysis and systematic review.

2. Original language title.

For reviews in languages other than English, this field should be used to enter the title in the language of the review. This will be displayed together with the English language title.

English

3. * Anticipated or actual start date.

Give the date when the systematic review commenced, or is expected to commence.

01/10/2018

4. * Anticipated completion date.

Give the date by which the review is expected to be completed.

30/06/2019

5. * Stage of review at time of this submission.

Indicate the stage of progress of the review by ticking the relevant Started and Completed boxes. Additional information may be added in the free text box provided.

Please note: Reviews that have progressed beyond the point of completing data extraction at the time of initial registration are not eligible for inclusion in PROSPERO. Should evidence of incorrect status and/or completion date being supplied at the time of submission come to light, the content of the PROSPERO record will be removed leaving only the title and named contact details and a statement that inaccuracies in the stage of the review date had been identified.

This field should be updated when any amendments are made to a published record and on completion and publication of the review. If this field was pre-populated from the initial screening questions then you are not able to edit it until the record is published.

The review has not yet started: No
Preliminary searches | Yes | Yes  
Piloting of the study selection process | Yes | No  
Formal screening of search results against eligibility criteria | No | No  
Data extraction | No | No  
Risk of bias (quality) assessment | No | No  
Data analysis | No | No  

Provide any other relevant information about the stage of the review here (e.g. Funded proposal, protocol not yet finalised).

6. * Named contact.
The named contact acts as the guarantor for the accuracy of the information presented in the register record.

Xi Chen

Email salutation (e.g. "Dr Smith" or "Joanne") for correspondence:
Miss Chen

7. * Named contact email.
Give the electronic mail address of the named contact.

zgykcx@126.com

8. Named contact address
Give the full postal address for the named contact.

No.415, Fengyang Road, Changzheng Hospital, Shanghai, China

9. Named contact phone number.
Give the telephone number for the named contact, including international dialling code.

13917605264

10. * Organisational affiliation of the review.
Full title of the organisational affiliations for this review and website address if available. This field may be completed as 'None' if the review is not affiliated to any organisation.

Shanghai Changzheng Hospital

Organisation web address:

Give the title, first name, last name and the organisational affiliations of each member of the review team. Affiliation refers to groups or organisations to which review team members belong.

Miss Xi Chen. Shanghai Changzheng Hospital
12. * Funding sources/sponsors.
Give details of the individuals, organizations, groups or other legal entities who take responsibility for initiating, managing, sponsoring and/or financing the review. Include any unique identification numbers assigned to the review by the individuals or bodies listed.

Key Weak Subject Construction Project of Shanghai Municipal Commission of Health and Family Planning?2016ZB0303?

13. * Conflicts of interest.
List any conditions that could lead to actual or perceived undue influence on judgements concerning the main topic investigated in the review.

None

Give the name and affiliation of any individuals or organisations who are working on the review but who are not listed as review team members.

State the question(s) to be addressed by the review, clearly and precisely. Review questions may be specific or broad. It may be appropriate to break very broad questions down into a series of related more specific questions. Questions may be framed or refined using PICO where relevant.

Comparison of cardiovascular safety of SGLT2 inhibitors in across racial groups in terms of All-cause mortality, CV death, heart failure, myocardial infarction and stroke.

Give details of the sources to be searched, search dates (from and to), and any restrictions (e.g. language or publication period). The full search strategy is not required, but may be supplied as a link or attachment.

A four-step search strategy is planned. Firstly, we will identify keywords and MeSH terms in PubMed. Secondly, the terms will be searched in PubMed, Scopus, the Cochrane Central Register of controlled trials (CENTRAL), Clinical Trials.gov and EudraCT. Thirdly, randomized clinical trials analyzing SGLT2 inhibitor cardiovascular safety in type 2 diabetes mellitus will be selected. Fourthly, references of included studies will be searched for additional papers. There will be no language or data restrictions.


17. URL to search strategy.
Give a link to a published pdf/word document detailing either the search strategy or an example of a search strategy for a specific database if available (including the keywords that will be used in the search
strategies), or upload your search strategy. Do NOT provide links to your search results.

Alternatively, upload your search strategy to CRD in pdf format. Please note that by doing so you are consenting to the file being made publicly accessible.

Do not make this file publicly available until the review is complete.

18. * Condition or domain being studied.

Give a short description of the disease, condition or healthcare domain being studied. This could include health and wellbeing outcomes.

Type 2 diabetes (T2DM) is a chronic, progressive disease, characterized mainly by persistent hyperglycemia. Sodium glucose co-transporter 2 (SGLT2) inhibitors are a novel class of oral antidiabetic drugs (OADs) for treating T2DM. With an action independent of insulin, they can significantly reduce glycated haemoglobin (HbA1c) levels in drug-naive patients or those inadequately controlled by metformin. But the adverse events are not fully illuminated.


Give summary criteria for the participants or populations being studied by the review. The preferred format includes details of both inclusion and exclusion criteria.

1. Patients with Type 2 Diabetes mellitus

20. * Intervention(s), exposure(s).

Give full and clear descriptions or definitions of the nature of the interventions or the exposures to be reviewed.

Treatment with sodium-glucose cotransporter-2 inhibitors.

21. * Comparator(s)/control.

Where relevant, give details of the alternatives against which the main subject/topic of the review will be compared (e.g. another intervention or a non-exposed control group). The preferred format includes details of both inclusion and exclusion criteria.

Other oral antidiabetic drugs or placebo.

22. * Types of study to be included.

Give details of the types of study (study designs) eligible for inclusion in the review. If there are no restrictions on the types of study design eligible for inclusion, or certain study types are excluded, this should be stated. The preferred format includes details of both inclusion and exclusion criteria.

Randomised controlled trials.


Give summary details of the setting and other relevant characteristics which help define the inclusion or exclusion criteria.

24. * Main outcome(s).

Give the pre-specified main (most important) outcomes of the review, including details of how the outcome is defined and measured and when these measurement are made, if these are part of the review inclusion criteria.
All-cause mortality, cardiovascular mortality and heart failure

Timing and effect measures

25. * Additional outcome(s).
List the pre-specified additional outcomes of the review, with a similar level of detail to that required for main outcomes. Where there are no additional outcomes please state ‘None’ or ‘Not applicable’ as appropriate to the review.
Myocardial infarction?stroke.

Timing and effect measures

26. * Data extraction (selection and coding).
Give the procedure for selecting studies for the review and extracting data, including the number of researchers involved and how discrepancies will be resolved. List the data to be extracted.
Two investigators will independently search papers, screen titles and abstracts of the retrieved articles, review the full-texts and select articles for their inclusion. All the investigators independently and in duplicate will extract data in a piloted form. The following information will be reported: 1) general information on the study (author, year of publication, study name, study type, follow-up period, number of patients, age, diabetes duration, ethnicity, sex, inclusion criteria of screened population, glucose-lowering medications at pre-screening, treatment of randomization, other anti-diabetes therapies allowed during the study); 2) end-points, including incidence of all-cause mortality, CV death, heart failure, myocardial infarction and stroke. The main paper and supplementary data will be searched; if data is missing, the study protocol and pharmaceutical industry website will be searched. Data will be cross-checked and any discrepancy will be discussed.

State whether and how risk of bias will be assessed (including the number of researchers involved and how discrepancies will be resolved), how the quality of individual studies will be assessed, and whether and how this will influence the planned synthesis.
Two review authors will independently assess the risk of bias in included studies by considering the following characteristics: selection bias, performance bias, detection bias, attrition bias, reporting bias, and any other biases. Disagreements will be resolved by discussion, with involvement of a third review author where necessary.

Give the planned general approach to synthesis, e.g. whether aggregate or individual participant data will be used and whether a quantitative or narrative (descriptive) synthesis is planned. It is acceptable to state that a quantitative synthesis will be used if the included studies are sufficiently homogenous.
A qualitative and quantitative analysis will be provided. The qualitative analysis will focus on study design, sample size, duration of follow-up; the characteristics of enrolled patients will be summarized. The
quantitative analysis will be performed through calculation of cardiovascular adverse effect ratio for the dichotomous. Heterogeneity between studies will be assessed by using I², with 50% or higher regarded as high. Publication bias will be assessed visually with funnel plots. All analyses will be two-sided and will be carried out using RevMan 5.3 (The Cochrane Collaboration) with a random-effect model; p 0.05 will be regarded as significant.

29. * Analysis of subgroups or subsets.

Give details of any plans for the separate presentation, exploration or analysis of different types of participants (e.g. by age, disease status, ethnicity, socioeconomic status, presence or absence or co-morbidities); different types of intervention (e.g. drug dose, presence or absence of particular components of intervention); different settings (e.g. country, acute or primary care sector, professional or family care); or different types of study (e.g. randomised or non-randomised).

by cardiovascular conditions

30. * Type and method of review.

Select the type of review and the review method from the lists below. Select the health area(s) of interest for your review.

**Type of review**
- Cost effectiveness  No
- Diagnostic  No
- Epidemiologic  No
- Individual patient data (IPD) meta-analysis  No
- Intervention  No
- Meta-analysis  Yes
- Methodology  No
- Narrative synthesis  No
- Network meta-analysis  No
- Pre-clinical  No
- Prevention  No
- Prognostic  No
- Prospective meta-analysis (PMA)  No
- Review of reviews  No
- Service delivery  No
PROSPERO
International prospective register of systematic reviews

No
Synthesis of qualitative studies
No
Systematic review
Yes
Other
No

Health area of the review
Alcohol/substance misuse/abuse
No
Blood and immune system
No
Cancer
No
Cardiovascular
No
Care of the elderly
No
Child health
No
Complementary therapies
No
Crime and justice
No
Dental
No
Digestive system
No
Ear, nose and throat
No
Education
No
Endocrine and metabolic disorders
Yes
Eye disorders
No
General interest
No
Genetics
No
Health inequalities/health equity
No
Infections and infestations
No
International development
No
Mental health and behavioural conditions
No
Musculoskeletal
31. Language.
Select each language individually to add it to the list below, use the bin icon to remove any added in error.

English
There is not an English language summary

32. Country.
Select the country in which the review is being carried out from the drop down list. For multi-national collaborations select all the countries involved.

China
33. Other registration details.

Give the name of any organisation where the systematic review title or protocol is registered (such as with The Campbell Collaboration, or The Joanna Briggs Institute) together with any unique identification number assigned. (N.B. Registration details for Cochrane protocols will be automatically entered). If extracted data will be stored and made available through a repository such as the Systematic Review Data Repository (SRDR), details and a link should be included here. If none, leave blank.

34. Reference and/or URL for published protocol.

Give the citation and link for the published protocol, if there is one

Alternatively, upload your published protocol to CRD in pdf format. Please note that by doing so you are consenting to the file being made publicly accessible.

No I do not make this file publicly available until the review is complete

Please note that the information required in the PROSPERO registration form must be completed in full even if access to a protocol is given.

35. Dissemination plans.

Give brief details of plans for communicating essential messages from the review to the appropriate audiences.

Do you intend to publish the review on completion?

No

36. Keywords.

Give words or phrases that best describe the review. Separate keywords with a semicolon or new line. Keywords will help users find the review in the Register (the words do not appear in the public record but are included in searches). Be as specific and precise as possible. Avoid acronyms and abbreviations unless these are in wide use.

Diabetes Mellitus; Cardiovascular , SGLT-2 inhibitors; ethnicity.

37. Details of any existing review of the same topic by the same authors.

Give details of earlier versions of the systematic review if an update of an existing review is being registered, including full bibliographic reference if possible.

38. * Current review status.

Review status should be updated when the review is completed and when it is published. For new registrations the review must be Ongoing.

Please provide anticipated publication date

Review_Ongoing

39. Any additional information.

Provide any other information the review team feel is relevant to the registration of the review.

40. Details of final report/publication(s).
This field should be left empty until details of the completed review are available.

Give the link to the published review.