

Data Sharing Statement

(was made according to ICMJE Requirements)

Izdatelstvo Meditsina journals are following publishing and journal best practices of the International Committee of Medical Journal Editors (ICMJE) (www.icmje.org), please complete a following statement (match with x if applicable).

1. Will individual participant data be available (including data dictionaries)?

- Yes
- No

2. What data in particular will be shared?

- All of the individual participant data collected during the trial, after deidentification;
- Individual participant data that underlie the results reported in this article, after deidentification (text, tables, figures, and appendices);
- Not available;

3. What other documents will be available?

- Study Protocol, Statistical Analysis Plan, Informed Consent Form, Clinical Study Report, Analytic Code;
- Study Protocol, Statistical Analysis Plan, Analytic Code;
- Study Protocol;
- Not available;

4. When will data be available (start and end dates)?

- Immediately following publication. No end date;
- Beginning 3 months and ending 5 years following article publication;
- Beginning 9 months and ending 36 months following article publication;
- Not applicable;

5. With whom?

- Anyone who wishes to access the data;
- Researchers who provide a methodologically sound proposal;

- Investigators whose proposed use of the data has been approved by an independent review committee (“learned intermediary”) identified for this purpose;
- Not applicable;

6. For what types of analyses?

- Any purpose;
- To achieve aims in the approved proposal;
- For individual participant data meta-analysis;
- Not available;

7. By what mechanism will data be made available?

- Data are available indefinitely at: http://_____ (Please, provide a Link);
- Proposals should be directed to _____@_____ (Please, provide an email). To gain access, data requestors will need to sign a data access agreement. Data are available for 5 years at a third party website http://_____ (Please, provide a Link);
- Proposals may be submitted up to 36 months following article publication. After 36 months the data will be available in our University's (Institute's) data warehouse but without investigator support other than deposited metadata;
- Information regarding submitting proposals and accessing data may be found at http://_____ (Please, provide a Link);

Corresponding author's signature _____

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