

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Comparison of bond failure rate of Orthodontic Brackets and Tubes bonded with Transbond XT or GC ortho connect adhesives, A six month randomized clinical trial

#### Protocol summary

##### Study aim

The aim of this 6-month randomized clinical trial was to compare the bond failure rate of orthodontic brackets and tubes bonded with GC ortho connect or Transbond XT adhesives.

##### Design

Randomized clinical trial with 2 intervention groups, Single blind, Randomization method by table of numbers, Including 100 patient

##### Settings and conduct

This study is done in Clinic of Bojnurd city school of dentistry. One hundred patients (50 maxillary and 50 mandibular arches) are evaluated. Overall, 1095 teeth are bonded (547 with GC ortho connect and 548 with Transbond XT). Patients are followed for 6 months and any attachment bond failures are registered. This study is single blind.

##### Participants/Inclusion and exclusion criteria

patients who need fixed orthodontic treatment class I, II, III malocclusions no buccal or labial restorations  
Extraction or non extraction orthodontic treatment plans

##### Intervention groups

In intervention groups, GC ortho connect adhesive is used on one side of dental arch and on other side  
Transbond XT adhesive is used.

##### Main outcome variables

Orthodontic bond failure

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20191221045838N1**

Registration date: **2020-04-25, 1399/02/06**

Registration timing: **retrospective**

Last update: **2020-04-25, 1399/02/06**

Update count: **0**

##### Registration date

2020-04-25, 1399/02/06

##### Registrant information

###### Name

mina moradi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 58 3229 6787

###### Email address

m.moradi@nkums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

##### Expected recruitment start date

2020-01-21, 1398/11/01

##### Expected recruitment end date

2020-03-17, 1398/12/27

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of bond failure rate of Orthodontic Brackets and Tubes bonded with Transbond XT or GC ortho connect adhesives, A six month randomized clinical trial

##### Public title

Bond failure rate of Orthodontic Brackets and Tubes

##### Purpose

Other

## Inclusion/Exclusion criteria

### Inclusion criteria:

patients who need fixed orthodontic treatment class I, II, III malocclusions no buccal or labial restorations  
Extraction or non extraction orthodontic treatment plans

### Exclusion criteria:

Teeth with facial restorations or congenital enamel defects  
Semi erupted teeth  
Second and third molars  
Surgically exposed teeth  
Occlusal interference  
Patients who need orthognathic surgery

## Age

No age limit

## Gender

Both

## Phase

N/A

## Groups that have been masked

- Participant

## Sample size

Target sample size: **100**

## Randomization (investigator's opinion)

Randomized

## Randomization description

2 intervention groups (group A&B), for example in A group Transbond XT is used on one side of dental arch and Gc ortho connect is used on the other side and in B group the opposite is done. Deployment in each group is done by simple randomization method and using table of numbers.

## Blinding (investigator's opinion)

Single blinded

## Blinding description

At first we inform the patient that 2 substances are to be used for treatment then we treat the patient without knowing which side of dental arch each substance is on.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of North Khorasan University of  
Medical Sciences

##### Street address

Shahryar street

##### City

Bojnurd

##### Province

North Khorasan

##### Postal code

9417694735

## Approval date

2019-10-23, 1398/08/01

## Ethics committee reference number

IR.NKUMS.REC.1398.072

## Health conditions studied

### 1

#### Description of health condition studied

Orthodontic treatment

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Orthodontic bond failure

#### Timepoint

6 months

#### Method of measurement

Check list

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

first Intervention group: Transbond XT adhesive from 3M unitek, U.S.A company. Randomly, attachments on one side of each jaw are bonded using this adhesive. The bond will be followed for 6 monthes and any failure is recorded.

#### Category

Treatment - Devices

### 2

#### Description

second Intervention group: GC Ortho Connect adhesive from GC Orthodontics, Japan company. On the other side of the jaw, attachments are bonded using this adhesive. The bond will be followed for 6 monthes and any failure is recorded. The bond will be followed for 6 monthes and any failure is recorded.

#### Category

Treatment - Devices

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Clinic of bojnourd school of dentistry

**Full name of responsible person**

Mina Moradi

**Street address**

School of dentistry, Arkan road.

**City**

Bojnourd

**Province**

North Khorasan

**Postal code**

9417694735

**Phone**

+98 58 3151 3322

**Email**

nkums.ac.ir@gmail.com

Mina Moradi

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

**Street address**

Shahryar street

**City**

Bojnurd

**Province**

North Khorasan

**Postal code**

9417694735

**Phone**

+98 58 3229 6787

**Fax****Email**

m.moradi@nkums.ac.ir

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Bojnourd University of Medical Sciences

**Full name of responsible person**

Kaveh Hojjat

**Street address**Deputy of research and technology, Nursing school,  
Shahryar st.**City**

Bojnourd

**Province**

North Khorasan

**Postal code**

7487794149

**Phone**

+98 58 3229 6769

**Email**

research@nkums.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Bojnourd University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding***empty***Country of origin****Type of organization providing the funding**

Academic

**Person responsible for general inquiries****Contact****Name of organization / entity**

Bojnourd University of Medical Sciences

**Full name of responsible person****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Bojnourd University of Medical Sciences

**Full name of responsible person**

Mina Moradi

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

**Street address**

Shahryar street

**City**

Bojnurd

**Province**

North Khorasan

**Postal code**

9417694735

**Phone**

+98 58 3229 6787

**Fax****Email**

m.moradi@nkums.ac.ir

**Person responsible for updating data****Contact****Name of organization / entity**

Bojnourd University of Medical Sciences

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Bojnurd

**Province**

North Khorasan

**Postal code**

9417694735

**Phone**

+98 58 3229 6787

**Fax****Email**

m.moradi@nkums.ac.ir

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

There is no further information

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable