

## Clinical trials operated in Egypt: big data analysis study

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### Abstract

Clinical trials are one of the most direction, approached by physicians/researchers in the medical sciences field. Clinicaltrials.gov is one of the most comprehensive databases around the world, in this field. It is including clinical trials going in United States, and outside United States. The website is mentioning that the database or US government is not scientifically responsible for these trials.

**“The U.S. government does not review or approve the safety and science of all studies listed on this website”** Egypt is one of the most important countries in the Middle East, with a long history in medical sciences as well. Provided in clinicaltrials.gov around 10 thousand trials going in Egypt.

**Goal of this study:** In this study the author analyzed the whole trials going in Egypt, to reflect the patterns and elements of these medical trials.

**Research method:** The method I used, is the quantitative analysis method to analyze all patterns of Egyptian clinical trials, such as:

- Physicians operated the clinical trial.
- Reasons and goals of each clinical trial (such as testing and experimenting a drug or a medication or a new way in treatment or diagnosis)

- Organization and affiliation related to responsibility or support for the clinical trial.
- Methods used and steps toward reaching a result for a clinical trial.
- Starting and processing and ending date of clinical trials.

To analyze all the above elements and patterns I analyzed all Egyptian clinical trials available in the database of [clinicaltrials.gov](https://clinicaltrials.gov) to approach the goal of this study, and to reflect the effort and role of Egyptian clinical trials and its core subjects.

The total number found for clinical trials operated at Egypt in the [clinicaltrials.gov](https://clinicaltrials.gov) database, was around 10530 (Ten thousand and five hundred and thirty) clinical trials.

**Conclusions:** The study and analysis of the whole clinical trials ran at Egypt, resulted and approached important conclusions, such as:

- The most rated subject is "Postoperative Pain" as this is the most condition/subject studied in clinical trials ran in Egypt.
- The majority of clinical trials in Egypt, started 1/1/2019. Number of these trials were 129 clinical trials.
- The majority of "primary completed date" was December the first, 2023.
- Number of trials completed at that date were 64 clinical trials in Egypt.
- The majority of "completion date" was December, 2023.
- Number of trials completed at that date were 72 clinical trials in Egypt.
- The majority of "first posted date" was May, 2023.

## Keywords

Clinical trials, big data, medical research, scientometric analysis, Egypt

## Introduction

As the medical research growth, the patterns of users (medical researchers/physicians) differ to approach the actual drugs, clinical findings, symptoms, diagnosis, etc.

One of the known and important fields in reaching results for new approaches when treating diseases, is the clinical trials processed inside or out side each country.

As the less documentation and controlling of clinical trials databases, the more concern of librarians and information providers, to guide users focusing on new approaches in medicine, and their needs checking these databases, for practice and research goals.

The [clinicaltrials.gov](https://clinicaltrials.gov) is one of the most comprehensive clinical trials databases. It is the official governmental United States clinical trials databases, with all other countries included, as volunteered by these countries.

Total of 10530 clinical trials operated in Egypt found and registered in [clinicaltrials.gov](https://clinicaltrials.gov), with detailed data.

As the data analysis is becoming again more important, and the importance of clinical trials, the author studied and analyzed the whole Egyptian trials, based on elements such as diagnosis, goals, drugs, symptoms, affiliated institutions, etc. for the goal of representing the importance of clinical research operated in Egypt by physicians/researchers and by institutions.

## Methodology

The author followed the quantitative analysis method to analyze all patterns of Egyptian clinical trials, available in the [clinicaltrial.gov](https://clinicaltrials.gov), such as:

- Physicians operated the clinical trial.
- Reasons and goals of each clinical trial (such as testing and experimenting a drug or a medication or a new way in treatment or diagnosis)
- Organization and affiliation related to responsibility or support for the clinical trial.
- Methods used and steps toward reaching a result for a clinical trial.
- Starting and processing and ending date of clinical trials.

To analyze all the above elements and patterns I analyzed all Egyptian clinical trials available in the database of [clinicaltrials.gov](http://clinicaltrials.gov) to approach the goal of this study, and to reflect the effort and role of Egyptian clinical trials and its core subjects.

The total number found for clinical trials operated at Egypt in the [clinicaltrials.gov](http://clinicaltrials.gov) database, was around 10530 (Ten thousand and five hundred and thirty) clinical trials.

### **Goal of study**

The goal of this study, is to reflect patterns and directions going in the clinical trials at Egypt, to present an image of the clinical research operated.

The whole tables of the analysis study for 10530 clinical trials going in Egypt, are not able to be presented in this research paper according to the number of pages, that exceed the Journal issue limitations. All tables are available by contacting the Author of this research. I provided the most frequent results in each pattern.

### **Findings and discussions**

#### **1- Conditions/subjects of Egyptian clinical trials:**

Each clinical trial would define what is this trial about, and conditions related to this trial.

The subjects and conditions of Egyptian clinical trials varied and branched into phenomena such as:

- Testing pain followed by a surgical operation.
- Infertility.
- Covid 19 in Egypt.
- Cerebral Palsy.
- Rheumatoid Arthritis

The following table is showing an example of “Conditions/subjects researched” which means the clinical trial is first have to decide what is the subject of the trial that is going to be researched, and under what condition(s) such as anesthesia. This means the trial is testing and researching what is happening during anesthesia in surgical operations to test a new method or generic drug to be experienced during that process.

The table will give how many clinical trials were operated for each subject/condition of the Egyptian clinical trials mentioned in [clinicaltrials.gov](http://clinicaltrials.gov)

Also in the following table, the author presented the most 11 subjects researched by Egyptian physicians during their clinical trials operated at Egypt.

**Table no. 1**

**Conditions/subjects of Egyptian clinical trials**

<b>Highest Conditions/subjects researched</b>	<b>Count of Conditions/subjects</b>
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Postoperative Pain	84
Infertility	62
Covid19	45
Anesthesia	38
Cerebral Palsy	26
Dental Caries	24
Post Operative Pain	22
Breast Cancer	22
Periodontitis	18
Cesarean Section Complications	18
Rheumatoid Arthritis	16

From the previous table, we can see that the most rated subject/condition studied in the Egyptian clinical trials, was "Postoperative Pain".

-Second subject researched was the "Infertility" in Egypt.

## **2- Examples of conditions, interventions, primary and secondary outcome measures:**

The way, tools, method, procedure, medications, and the outcomes of a clinical trial, were important elements to be analyzed by the author and to represent how the Egyptian clinical trials were operated and proceeded.

The following table is showing an example of "Conditions/interventions/Primary Outcome Measures/ Secondary Outcome Measures." which means the clinical trial is first have to decide what are the detailed steps and procedures that is going into the applying of that trial, and follow these steps to bring the result and outcomes. For example, one or more clinical trials researched

“Cervical Radiculopathy” which is the pinched nerve, and this condition results in a pain in the lower back causing stressful and frequent pain. This pain and condition require first a “Proprioceptive neuromuscular” which would be the intervention decided by doctors to start using a stretching technique to remove or reduce the pain.

After 6 weeks of that specific trial the “primary and secondary outcome measures” will be defined. Using LASER technique to measure the ability of the patient to adapt with the movement of his/her body and to see the reduced sense of pain, and how far it was reduced.

Also the following table will represent examples of these conditions, interventions, primary and secondary outcome measures.

### Table no. 2

Examples of conditions, interventions, primary and secondary outcome measures:

<b>Conditions</b>	<b>Interventions</b>	<b>Primary Outcome Measures</b>	<b>Secondary Outcome Measures</b>
Laparoscopy.	PROCEDURE: lap fundus-calot cholecystectomy PROCEDURE: open cholecystectomy .	duration of operation 2 hours.	
Symptomatic Periapical Periodontitis.	DRUG: Amoxicillin/Clavulanate Potassium 875 mg-125 mg oral tablet	Postoperative pain, Postoperative pain will be measured by a numerical rating	Swelling, The occurrence of Swelling will be measured by a questionnaire., Up to 7 days after

	DRUG: Oral placebo.	scale (NRS), Up to 7 days after endodontic treatment.	endodontic treatment.
Steatohepatitis, Nonalcoholic.	DRUG: Control group DRUG: Montelukast group.	Fibro-scan score, change in liver stiffness measurement (Fibro-scan score), At baseline and after 12 weeks of intervention Liver Panel, Alanine aminotransferase (ALT) and Aspartate Aminotransferase (AST) will be evaluated in U/L, after 12 weeks of intervention.	HOMA-IR, Homeostatic Model Assessment of Insulin Resistance, after 12 weeks of intervention 8-OHdG, Serum level of 8-OHdG, after 12 weeks of intervention TNF-Alpha, Serum level of TNF-Alpha, after 12 weeks of intervention hyaluronic acid, Serum level of hyaluronic acid, after 12 weeks of intervention TGF- $\beta$ 1, Serum level of TGF- $\beta$ 1, after 12 weeks of intervention Assessment of drugs tolerability: Side effects, Side effects of montelukast, after 12 weeks of intervention.



Traumatic Urethral Stricture, Male, Overlapping Sites.	PROCEDURE: urethroplasty.	UROFLOWMETERY, the speed and feasibility of micturition measured by non invasive pressure flow study Q max more than 10ml/sec, three months after the operation postmicturition residue, abdominal ultrasound done to evaluate PMR, three months after the operation Retrograde Urethrogram RUG, contrast study to evaluate and delineate the urethra, three months after the operation.	
Previous Incision Scar; Previous Cesarean Section.	BIOLOGICAL: platelet rich plasma gel BIOLOGICAL: saline.	Efficacy of PRP in Wound healing in cesarean section by 100 mm visual analog scale, Efficacy of PRP in Wound healing in cesarean section by 100 mm visual	Assessment of the Cosmetic results of the wound by Modified Vancouver scar scale, Assessment of the Cosmetic results of the wound by Modified Vancouver

		analog scale (VAS) for wound healing, one month.	scar scale, one month.
Cervical Radiculopathy.	OTHER: Proprioceptive neuromuscular facilitation; OTHER: Passive mobilization.	Cervical pain, Score on numeric pain rating scale (points), 6 weeks Cervical disability, Disability will be measured with Northwick Park neck pain Questionnaire., 6 weeks.	Cervical proprioception, Cervical joint position error will be measured with laser pointer., 6 weeks.
Macula Hole Retinal Detachment Myopic Macular Degeneration.	PROCEDURE: Recurrent opened macular hole.	Anatomical restoration of macular hole closure, Closure of the macular hole, 6 months.	Functional restoration after closure of the macular hole, Improvement of the best corrected visual acuity (BCVA), 6 months Functional restoration after closure of the macular hole, Any improvement of the waves in the electrophysiological (ERG) study., 6 months.
Chronic Anal Fissure.	DEVICE: shock master (shock waves device).	VAS, assessment of pain, up to 3 months.	wexener scale, assess the constipation, up to 3 months.

Cataract Glaucoma, Open-Angle.	PROCEDURE: combined phacoemulsifica tion and ultrasound ciliary platy (Phaco- UCP) PROCEDURE: Phacoemulsifica tion alone.	Reduction in intraocular pressure, Qualified Success was defined as an IOP reduction of at least 20 % from baseline value, with an IOP that is between 6 - 21 mm Hg, without the need for additional antiglaucoma medications or glaucoma surgery, 18 months postoperativered uction in r the number of antiglaucoma medications., reduction of the number of antiglaucoma medication or at least no increase in the number, 18 months postoperative.	BCVA improvement, improvement of best corrected visual acuity, 18 months postoperativeintrao perative and postoperative complications., hyphema or vitreous hemorrhage necessitating surgical intervention, choroidal hemorrhage, chronic uveitis, endophthalmitis, hypotony (IOP $\hat{\alpha}\%$ 5 mm Hg), phthisis, IOL dislocation, and retinal detachment., intraoperative and 18 months postoperative.
GynecomastiaT horacic Interfacial Plane Block Thoracic Paravertebral Block Anesthesia.	DRUG: Tumescent local anesthesiaDRUG: Thoracic paravertebral blockDRUG: Thoracic	The amount of intraoperative fentanyl requirement (mg), If the patient complains from pain, fentanyl	Degree of patient's satisfaction, Patient satisfaction before discharge using a 5- point score, with (0 = very dissatisfied, 1 = dissatisfied, 2 =

	interfacial plane block.	25½g intravenously will be administrated., 3 hours.	neither satisfied nor dissatisfied, 3 = satisfied and 4 = very satisfied), 6 hours.
Spinal Anesthesia Suitability for Abdominoplasty.	DRUG: Propofol 10 Mg/mL Intravenous Emulsion.	Change in Pain sensation: Visual analogue scale, Visual analogue scale for Pain assessment from 1 with least pain to 10 with maximum pain felt, pain assessment during the operation and every 4 hours for 12 hoursPatients satisfaction: Satisfaction score changes, Satisfaction score with maximum score is fully satisfied and least is completely disagree, Intraoperative assessment every 30 minutes till end of surgery.	
Hysterectomy Laparoscopy Uterine Bisection Large Uteri.	PROCEDURE: Vaginal bisection Procedure: Abdominal bisection.	Retrieval time of uterus, Time from end of colpotomy to extraction of uterus, 6	Injury of other organs, Number of cases with intraoperative injuries, 6 months.

		months Blood loss, Amount of blood in suction, 6 months.	
Beta Blocker Toxicity.	DRUG: nonselective beta blocker DRUG: cardio-selective beta blocker group DRUG: alendronate sodium.	Number of patients with fracture in each group, the exact number of patients with fracture in each group, 1 year.	
Peripheral Neuropathy Due to Chemotherapy	DIETARY_SUPPLE MENT: low dose N-acetylcysteine DIETARY_SUPPLE MENT: high dose N-acetylcysteine DRUG: Paclitaxel	Incidence of chemotherapy induced- peripheral neuropathy, Number of patients reported neuropathy from paclitaxel, up to 12 weeks.	Severity of chemotherapy induced-peripheral neuropathy, severity of paclitaxel induced peripheral neuropathy using NCI-CTCAE criteria, at baseline and before each cycle up to 12 week Adverse effects, any adverse/ side effect will be evaluated, at baseline and each cycle up to 12 week severity of chemotherapy induced-peripheral neuropathy, severity of chemotherapy induced-peripheral neuropathy using modified total neuropathy score

			<p>,Each neuropathy item is scored by a physician on a 0-4 scale the scores are summed to obtain a total score, modified total neuropathy score score ranges from 0-24 with higher total scores indicate more severe neuropathy., at baseline, at the end of 6 cycle and at the end of 12 cycles</p>
<p>Dialysis; Complications.</p>	<p>OTHER: high dialysate Na OTHER: low dialysate Na.</p>	<p>Change in dialysis recovery time, by assessing the patients' responses to the single open-ended question, "How long does it take you to recover from a dialysis session?", baseline, weeks 4 and 8.</p>	<p>Change in plasma sodium concentration, measuring plasma sodium concentration, baseline, weeks 4 and 8 Change in the inter-dialytic weight gain, measuring the inter-dialytic weight gain, 8 weeks Change in blood pressure (systolic, diastolic, mean), measuring in blood pressure (systolic, diastolic, mean), 8 weeks Occurrence of intradialytic hypotension, incidence of</p>

			intradialytic hypotension, 8 weeks Occurrence of muscle cramps, incidence of muscle cramps, 8 weeks Occurrence of headache, incidence of headache, 8 weeks.
Analgesia, Epidural.	DRUG: ultrasonography -guided TAP block DRUG: Caudal epidural block.	Postoperative analgesia., time for first analgesic request, 24 hours.	Postoperative analgesia, total amount analgesic administered, 24 hours Postoperative pain, using the FLACC scale. Rate child on each of the five categories (face, legs, arms, crying, consolability). Each category is scored on the 0 to 2 scale. Add the scores together (for a total possible score of 0 to 10)., 24 hours.
Hepato-splenomegaly Dysostosis Multiplex Seizures Mental Retardation.		Development of a new MS-based biomarker for the early and sensitive diagnosis of GM1/GM2-Gangliosidosis from blood, new methods, like mass-	Testing for clinical robustness, specificity and long-term stability of the biomarker, the goal of the study to identify and validate a new biochemical marker from the blood of the affected

		spectrometry give a good chance to characterize specific metabolic alterations in the blood of affected patients that allow diagnosing in the future the disease earlier, with a higher sensitivity and specificity., 24 months.	patients helping to benefit other patients by an early diagnose and thereby with an earlier treatment., 36 months
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From the previous table, the following were noticed and analyzed:

-Laparoscopy was one of the procedures going to examine organs in abdominal area of human body, in the Egyptian clinical trials. This procedure is used in different surgeries, such as remove of gallbladder. In this clinical trial mentioned, the duration time was 2 hours.

-Another condition studied was Symptomatic Periapical Periodontitis, which is a type of inflammation around the teeth. In this example, the trial was based on using the drug "Amoxicillin/Clavulanate Potassium 875 mg-125 mg oral" to examine the result after 7 days of treatment.

### 3-Start date

Clinical trials in Egypt started long time ago. The starting date of the oldest Egyptian clinical trial registered in clinicaltrials.gov was September 1989.



The following table is showing an example of “**start dates**” of Egyptian clinical trials and also how many clinical trials started at each date.

The table will give examples of the highest start dates that had the most Egyptian clinical trials ran at these dates.

**Table no.3**

**Egyptian clinical trials starting dates**

<b>Highest Start Date</b>	<b>Count of clinical trials started at that date</b>
1/1/2019	129
1/1/2018	105
1/1/2022	103
1/1/2023	94
1/1/2021	91
1/1/2020	86
6/1/2021	68
9/1/2020	64
4/1/2023	63
11/1/2022	62
6/1/2022	62
12/1/2020	60
12/1/2021	58
3/1/2022	58

From the previous table: The majority of clinical trials in Egypt, started 1/1/2019. Number of these trials were 129 clinical trials.

#### **4- Primary completion date**

The essential date of completing a clinical trial is very important to show when the trial was finished, and to follow up with an explanation of the results.

The following table shows an example of “**primary completion dates**” which means when the clinical trial was mainly completed. The table has examples of completion dates and number of Egyptian clinical trials completed each year.

The next table represents an example of the highest completion dates, of the Egyptian clinical trials.

**Table no. 4**

**Primary completion date**

<b>Highest primary Completion Date</b>	<b>Count of clinical trials primary completed at these dates</b>
12/1/2023	64
12/1/2021	63
2023-12	61
12/1/2022	55
10/1/2023	53
1/1/2020	52
4/1/2024	51
6/1/2022	50
1/1/2023	49
3/1/2022	47
8/1/2022	45
3/1/2021	45
2024-03	45
6/1/2023	44
8/1/2023	44

2/1/2023	44
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The previous table is showing: The majority of “primary completed date” was December the first, 2023.

Number of trials primary completed at that date were 64 clinical trials in Egypt.

## 5-Completion date

The following table is showing an example of “final completion dates” which means when the clinical trial was finally completed. The table has examples of final completion dates and number of Egyptian clinical trials completed each year.

The next table represents an example of the highest final completion dates, of the Egyptian clinical trials.

**Table no. 5**

### Final completion date of Egyptian clinical trials

Highest completion Date	Count of Completion Date
2023-12	72
12/1/2023	68
12/1/2022	63
12/30/2023	54
12/1/2021	54
12/30/2022	50
3/1/2022	50
3/1/2021	49
2019-12	48
1/1/2023	47
12/1/2020	47

2022-12	46
4/1/2024	45
9/1/2023	45
10/1/2023	44
9/1/2022	43

The previous table is showing: The majority of “completion date” was December, 2023. The Number of trials completed at that date were 72 clinical trials in Egypt.

### 6-First posted

Posting the announcement and data about starting a clinical trial, give the physicians around the world that there is a trial starting in a specific subject, which help in reducing redundancy of starting an exact clinical trial at the same country.

The table will reflect examples of the highest dates of posting an announcement, and number of Egyptian clinical trials posted at each date.

**Table no. 6**

#### **Date of first post about an Egyptian clinical trial**

<b>Highest first Posted date</b>	<b>Count of clinical trials First Posted at that date</b>
5/6/2023	26
8/14/2023	26
9/21/2023	23
11/7/2023	22
1/22/2021	21
8/21/2023	20
1/4/2023	19

5/3/2023	19
8/2/2023	19
8/5/2020	18
6/27/2023	18
6/16/2020	17
8/1/2023	17
8/19/2020	16

The previous table is showing: The majority of "first posted date" was May, 2023.

Number of trials posted at that date were 26 clinical trials in Egypt.

## 7-Latest "Start date" and oldest "start date"

When searching <http://clinicaltrials.gov> I found that the latest date registered to start an Egyptian clinical trial is going to be December 2024. The earliest date registered was September 1989 and primary completed in May 2000.

**Table no. 7**

### Latest "Start date" and oldest "start date"

Start Date	Primary Completion Date	Completion Date
2024-12	2025-02	2025-03
1989-09	2000-05	

## 8-Sponsor institutions:

Organizations and institutions sponsored the clinical trials in Egypt, varied and these bodies mainly were universities. The next table is to show the highest sponsored organizations and number of Egyptian clinical trials sponsored by each corporate body.

**Table no. 8**

### Sponsor institutions

Highest sponsors	Count of clinical trials
Cairo University	2071
Assiut University	1359
Ain Shams University	975
Mansoura University	673
Sohag University	477
Tanta University	402
Alexandria University	313

Zagazig University	232
Al-Azhar University	218
Kasr El Aini Hospital	173
Minia University	165
Beni-Suef University	151
Benha University	127
Ain Shams Maternity Hospital	99

The previous table is showing: The majority and highest corporate body sponsored the Egyptian clinical trials was Cairo University. Number of trials at this corporate body was 2071 in Egypt.

## 9- Clinical status

Between starting a clinical trial and completing it, a time span and a long process. The next chart is representing status of Egyptian clinical trials.



**Chart no. 1**

### **Egyptian clinical trials status**

<b>Status of clinical trial</b>	<b>Count</b>
COMPLETED	5495
UNKNOWN	2319
RECRUITING	1772
NOT_YET_RECRUITING	417
ACTIVE_NOT_RECRUITING	290
ENROLLING_BY_INVITATION	95
TERMINATED	65
WITHDRAWN	52
SUSPENDED	20
AVAILABLE	3
APPROVED_FOR_MARKETING	2
<b>Grand Total</b>	<b>10530</b>

The previous table is showing: The majority of clinical trials are “completed” Number of trials completed is: 5495 clinical trials in Egypt.

Also showing other status of Egyptian clinical trials such as: clinical trials recruiting, and these are repeated for some reasons. Also the chart is showing Egyptian clinical trials that are approved for marketing, which means the trial results are approved and ready to be applied.

## **Conclusions**

1-The most rated subject is “Postoperative Pain” as this is the most condition/subject studied in clinical trials ran in Egypt.

2-The majority of clinical trials in Egypt, started 1/1/2019. Number of these trials were 129 clinical trials.



3-The majority of “primary completed date” was December the first, 2023.

4-Number of trials completed at that date were 64 clinical trials in Egypt.

5-The majority of “completion date” was December, 2023.

6-Number of trials completed at that date were 72 clinical trials in Egypt.

7-The majority of “first posted date” was May, 2023.

8-Number of trials completed at that date were 26 clinical trials in Egypt.

9-The majority “sponsor” was Cairo University.

10-Number of trials at this corporate body was 2071 in Egypt.

11-The majority of clinical trial are “completed”

12-Number of trials completed is: 5495 clinical trials in Egypt.

## References

*ClinicalTrials.gov*. Retrieved June 26, 2024, from <https://clinicaltrials.gov/>